(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 March 2001 (29.03.2001)

PCT

(10) International Publication Number
WO 01/21246 A1

(51) International Patent Classification[7]: A61M 29/00

(21) International Application Number: PCT/US00/25678

(22) International Filing Date:
19 September 2000 (19.09.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/154,969 20 September 1999 (20.09.1999) US

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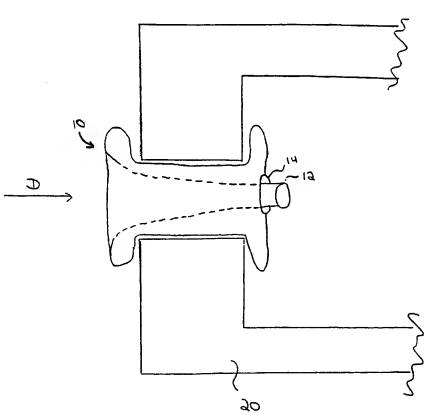
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,

[Continued on next page]

(54) Title: ANNULOTOMY CLOSURE DEVICE



(57) Abstract: A system for sealing a hole in a body, comprising a generally cylindrical mesh (10) formed from a plurality of helical strands (13) which is inserted into the hole, with at least one end of the cylindrical mesh being moved least partially through an interior portion of the cylindrical shaped mesh such that the mesh expands radially outwards against sides of the hole.

WO 01/21246 A1

IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ANNULOTOMY CLOSURE DEVICE

CROSS-REFERENCES TO RELATED APPLICATIONS

The present application is a continuation application claiming priority from Provisional U.S. Patent Application No. 60/154,969 filed September 20, 1999, which is incorporated herein by reference in its entirety for all purposes.

TECHNICAL FIELD

The present invention relates to systems for sealing holes in body parts and to sealing surgically formed holes in a bony structure in general and in particular to systems for providing closure of a surgical access hole in an intervertebral disc following an annulotomy.

BACKGROUND OF THE INVENTION

Each intervertebral disc has a firm outer layer, called the annulus fibrosus, and a gelatinous interior called the nucleus pulposus. The annulus fibrosus acts as a semi-rigid elastic pressure vessel to contain the nucleus pulposus, therefore creating a compliant interface between the relatively rigid vertebrae above and below each disc. Adjacent to each disc, a pair of nerve roots pass from the spinal canal through apertures called intervertebral foramen on each side of the spine. Due to the location of the nerve roots, they are vulnerable to pressure from a herniated disc. In certain instances, the herniated section of the annulus fibrosus may become thinner through the transverse plane of the disc.

When a partial intervertebral discectomy is performed, the offending portion of the herniated disc is excised. In this procedure, the surgeon must first make an appropriate incision through the skin and other tissue layers, and then typically create an access hole into the herniated annulus (an annulotomy) to treat the offending tissue. Such access holes are created with a variety of surgical instruments including scalpels, probes, trephines, etc., and the access hole may range in size from 3 to 6 mm in diameter. Furthermore, as instruments are passed through the circular hole, the hole may become enlarged or elongated in nature upon completion of the procedure. Upon entry to the interior annular space, the offending tissue is then manipulated and/or removed by the surgeon. In current practice, the surgeon closes the outer wounds created by the procedure, but leaves the access hole open. Due to the semi-rigid nature of the annular tissue, closure by means of

traditional tissue approximation techniques, such as suturing, is nearly impossible. Closure is further complicated by the proximity of nerves and the depth of the access hole below the surface of the skin. As a complication of disc excision surgery, such annular defects can represent a potential liability with respect to subsequent recurrent disc herniations. This is due to the fact that the annular defect between the interior space of the annulus and the area adjacent to the annulotomy allows for possible future passage of nucleus pulposus tissue therethrough. During the course of normal movement by the patient during the post operative healing phase, (which may last up to several weeks), relatively high fluidic pressures can be generated within the annular space. These high pressures can cause the nucleus pulposus to be extruded through the open hole and impinge upon nearby nerves, thus causing a reoccurrence of the original symptoms that the surgeon intended to treat.

SUMMARY OF THE INVENTION

The present invention provides methods and apparatus for the closure of holes, including surgical access holes formed in a rigid or semi-rigid body, and is particularly useful in closing a surgical access hole in an intervertebral disc. As such, the present invention provides systems of annulotomy closure which reduce the risks of reherniation.

In a first aspect of the invention, a system comprising a generally cylindrical-shaped mesh is used to seal a hole which may be a surgical access hole. The mesh itself may preferably comprise a braid of separate strands with each strand following a helical path around a central longitudinal axis such that the mesh comprises a flexible tube of interwoven springs. In various optional aspects, at least one of the proximal (i.e.: outer surface) and distal (i.e.: deep) ends of the cylindrical-shaped mesh may optionally be covered by an end-cap which may be made of the mesh material.

In this first aspect of the invention, the mesh cylinder may first be inserted into the hole in the annulus and positioned such that both the proximal and distal ends of the mesh extend somewhat out of the respective proximal and distal ends of the hole. Thereafter, the proximal end of the mesh can be pushed longitudinally in a distal direction through the "interior" of the mesh (ie: through the central tube defined by the cylindrically-shaped mesh body) to a distance such that the proximal end may pass fully through the interior of the mesh, and extend in a distal direction at least partially past the distal end of the mesh. This causes the mesh cylinder to become folded over upon itself, with one end of the mesh being

folded into the center of the mesh.

In further aspects, the distal end of the cylindrical-shaped mesh may be pulled in a proximal direction such that a region of the mesh adjacent the distal end expands radially outwards, bulging around the inner (distal) perimeter of the distal end of the hole. Furthermore, the proximal end of the cylindrical mesh can be pushed in a distal direction such that a portion of the mesh adjacent the proximal end of the hole expands radially outwards, bulging around the outer (proximal) perimeter of the hole.

The present invention also provides a method of sealing a hole in a body part, comprising introducing a generally cylindrical shaped mesh into the hole and then moving at least one end of the cylindrical shaped mesh at least partially through an interior portion of the cylindrical shaped mesh such that the mesh expands radially outwards against sides of the hole.

The pushing of the proximal end in a distal direction and/or the pulling of the distal end in a proximal direction will preferably tend to cause the cylindrical shaped mesh to expand radially outwards, thereby firmly anchoring the mesh against the walls of the hole in the annulus.

In further preferred aspects, the proximal and distal ends of the cylindrical mesh can be formed to be of a fixed diameter such as by the attachment or formation of a non-expandable ring thereon.

A plurality of suture/tethers may optionally be attached to the distal end of the mesh to pull it in a proximal direction. Tubular inserters for positioning the cylindrical mesh within the bore of the hole may also be provided.

In various aspects, the diameter of one end of the mesh is constructed to be smaller than that of the other end of the mesh such that a first end can easily be pulled through a second end of the mesh. In specific preferred aspects, the diameter of the proximal end will be smaller than that of the distal end.

In an alternate method of employing the present invention, each of the proximal and distal ends of the cylindrical mesh may be pulled partially into the center of the cylindrical mesh (ie: pulled partially through the interior tube defined by the mesh body) such that the proximal end is moved distally and the distal end is moved proximally, towards, or optionally passing through, one another.

In a second aspect of the invention, various systems for sealing a surgically cut hole in the disc are provided comprising a generally planar sheet-like material which is cut or

formed into a circular pattern having a plurality of radially extending "flower petal"-type extensions. These petals are first bent radially inwards giving the structure a generally conical shape. The petals will then tend to flex radially outwards when released after the device has been place into the hole in the annulus, thereby sealing the hole. Specifically, the resultant conical structure of the second aspect of the invention is inserted longitudinally into the hole in the annulus and is then released such that the petals will tend to flex radially outwards, thereby anchoring the structure in position in the hole. In this aspect of the invention, the spaces cut between successive radially extending petals may be adapted to permit some fluid movement therethrough. In various designs of this aspect of the invention, a plurality of such sheet-like "flower petal" structures are bent into a conical shape and are inserted in succession into the hole.

Advantages of both aspects of the present invention include its encouragement of rapid healing by providing a lattice structure to enhance tissue growth. Moreover, the present annulotomy closure systems are also able to accommodate the various sizes and geometries of annular holes that may be encountered by the surgeon. Furthermore, the present annulotomy closure systems all provide compensation for normal movement during patient healing since the system itself remains transversely flexible but is positionally stable along its longitudinal axis. A further advantage of the present system is that should any portion of the mesh remain on the outside of the hole on the annulus, this would be atraumatic to adjacent nerves in close proximity to the device due to the soft and flexible nature of the mesh material.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a cylindrical shaped mesh.

Fig. 2 is a sectional side elevation view of the cylindrical mesh of Fig. 1 positioned in a hole in the annulus of an intervertebral disc.

Fig. 3 is a sectional side elevation view of a tubular shaped mesh.

Fig. 4 is a sectional side elevation view of the mesh of Fig. 3 received through a hole in an intervertebral disc.

Fig. 5 is the system of Fig. 4 after the distal end of the mesh has been pulled in a proximal direction, causing a portion of the mesh to expand around the inner surface of the hole.

Fig. 6 shows the system of Fig. 4 after the proximal end of the mesh has been pushed in a distal direction, causing a portion of the mesh to expand around the outer surface of the hole.

Fig. 7 shows the system of Fig. 6 after the proximal end of the mesh has been pushed distally through the distal end of the mesh.

Fig. 8 is a perspective view of a system for delivering the tubular mesh illustrated in Figs. 3 to 7.

Fig. 9 is a sectional side elevation view of the mesh of Fig. 1 in a first position.

Fig. 10 is a sectional side elevation view of the mesh of Fig. 1 in a second position.

Fig. 11 is a perspective view of an alternate aspect of the first embodiment of the present invention.

Fig. 12A is a sectional side elevation view of the system of Fig. 11 positioned in the annular hole.

Fig. 12B is a side elevation view corresponding to Fig. 12A, but with the system distally advanced into the hole.

Fig. 13A is a front elevation view of a second aspect of the present invention.

Fig. 13B is a side elevation view of the device of Fig. 13A.

Fig. 14 is a side elevation view of the system of Figs. 13A and 13B deformed into a conical shape and inserted into a surgical access hole in an intervertebral disc.

Fig. 15 is a front view of different designs for the second aspect of the present invention shown in Figs. 13A and 13B.

Fig. 16 is a side elevation view of a plurality of devices as illustrated in Figs. 13A, 13B or 15 deformed into conical shapes and inserted into a surgical access hole in an intervertebral disc.

Fig. 17 corresponds to Fig. 16 but illustrates the apexes of the conical shapes pointing in opposite directions.

Fig. 18 is a side elevation view of a pair of systems as illustrated in Figs. 13A, 13B or 15 for insertion into a surgical access hole in oppositely facing directions.

Fig. 19 shows a side view of the system arrangement of Fig. 18, but with the conical shaped structures deformed into an inverted position.

Fig. 20 shows a side view and an enlarged close-up view of the conical shaped structures of Fig. 18 and 19 interlocked together.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

The present invention provides methods and apparatus for sealing holes in various bony structures. In a preferred aspect, the present invention provides methods and apparatus for sealing a surgical hole drilled in a patient's annulus. As such, the present invention is ideally suited to seal a hole drilled in an intervertebral disc such that nucleus pulposus on the inside of the disc cannot seep or flow through the hole to the outside of the disc as the disc is compressed during normal movement. The present system is not limited only to sealing holes which have been drilled in an annulus, but may also be used to seal naturally occurring holes as well. Moreover, the present invention is not limited to sealing holes in the annulus alone but may be used to seal any hole, thereby inhibiting the passage of soft tissue therethrough.

Fig. 1 shows a generally cylindrical tubular mesh which is comprised of a multiplicity of monofillament or multifilliar strands 13 of suture-type material, each following a helical path about central longitudinal axis A. Mesh 10 has a proximal end 12 and a distal end 14. An advantageous property of mesh 10 is that as proximal end 12 and distal end 14 are moved closer together with respect to one another, mesh 10 will tend to expand radially outwards, widening in its diameter D.

In a preferred design, the mesh diameter D is approximately 1 to 8, millimeters, and more preferably about 3 millimeters when mesh 10 is in its relaxed state, (i.e.: when ends 12 and 14 are not being pushed together). When ends 12 and 14 are pushed together, however, diameter D of mesh 10 may reach 9 millimeters. In preferred designs, strands 13 may each be made of 0.15 millimeter polypropylene sutures. Other materials having suitable dimensions, bioabsorption, strength, spring rate or radiopacity may also be used.

In an optional aspect, proximal end 12 may be sealed, for example with a mesh closure positioned thereover. In another optional aspect of the invention, as will be explained, ends 12 and 14 may be formed to be non-expandable such that their diameters do not change as ends 12 and 14 of mesh 10 are pushed together relative to one another. For example, a solid ring may be formed at, or attached to, one or both of ends 12 and 14.

Fig. 2 illustrates a preferred method of operating the present invention, as follows. Mesh 10 is inserted longitudinally in distal direction D into surgically cut hole 21 in disc 20 such that proximal end 12 and distal end 14 extend out of hole 21 past outer surface 11 and inner surface 13 of hole 21 in disc 20 as defined by walls 22 as shown.

As is shown in Fig. 3, mesh 10 may optionally be fitted with a plurality of sutures/tethers 30 which are tied to the distal end 14 of mesh 10 and extend through the central chamber of mesh 10 as shown.

As shown in Fig. 4, mesh 10 is inserted in a distal direction D such that it is positioned in hole 21 with its distal end 14 extending past inner surface 13 of disc 20, and with its proximal end 12 extending past outer surface 11 of disc 20. The placement of distal end 14 at an appropriate distal depth such that a portion of mesh 10 extends in a proximal direction from outer surface 11 of hole 21 can be enhanced through various visualization techniques such as shaft depth markers or endoscopic, radiographic or ultrasound methods.

For clarity of illustration, to show both the side walls of hole 21 and mesh 10, the following Figs. show a small clearance between the walls of the mesh and the walls of the hole when the mesh has been expanded into position, (for example, by pushing proximal end 12 and distal end 14 together, or through the central longitudinally extending chamber of the mesh). It is to be understood that such clearance would not exist as mesh 10 becomes anchored against walls 22 when positioned.

Following the step shown in Fig. 4, suture tethers 30 are preferably pulled in proximal direction P while proximal end 12 is held in a fixed position relative to hole 21, (as shown in Fig. 5). When pulled by suture/tethers 30, distal end 14 will tend to move in proximal direction P such that mesh 10 will expand radially in diameter in the region of the mesh pushing outwardly against the inner surface of hole 21, and forming a bulge 15 at mesh distal end 14 against inner surface 13.

Thereafter, as is shown in Fig. 6, a rod 40, (which can be used to hold proximal end 12 in position relative to hole 21 while pulling on suture tethers 30 as illustrated in Fig. 5), can be used to push distal end 12 in distal direction D such that the region of mesh 10 between distal end 12 and outer surface 11 will tend to expand around the proximal end of hole 21, forming a bulge 17 against outer surface 11, as shown. In this aspect of the invention, proximal end 12 may optionally be formed to be non-expandable, for example by attachment to a fixed diameter ring therearound.

The effect of mesh 10 being deformed to form respective bulges 17 and 15 at the outer surface 11 and inner surface 13 of disc 20 will be to hold mesh 10 at a fixed longitudinal position relative to hole 21 (such that it doesn't move in either a proximal or distal direction).

Thereafter, as is shown in Fig. 7, distal end 12 may optionally be pushed longitudinally in distal direction D such that is passes through the center of the mesh such

that it extends out through distal end 14. In this aspect of the invention, distal end 12 may be formed to be non-expandable and have a slightly larger diameter than that of distal end 14 such that distal end 12 can pass through distal end 14 and be snap-fit through the opening of distal end 14.

Fig. 8 is a perspective view of a system for delivering and positioning mesh 10 into hole 21 of the disc 20 as illustrated in Figs. 1 to 7. Rod 40 may be used to support proximal end 12 at a fixed position relative to hole 21 when suture/tethers 30 are used to pull distal end 14 in a proximal direction. In addition, rod 40 can be used to push proximal end 12 through distal end 14, as was shown in Fig. 7. Suture/tethers 30 which may preferably comprise three tethers anchored to distal end 14 at locations which are spaced radially 120° apart may be received over push rod 40 as shown. A tubular inserter 35 is then received thereover. Inserter 35 may be used for pushing mesh 10 against the proximal end of hole 21 as is shown in Fig. 6 so as to create bulge 17. Suture tethers 30 may preferably be cut or removed after insertion.

In another aspect of the invention, as illustrated in Figs. 9 and 10, each of the proximal and distal ends of the cylindrical mesh may be pulled inwardly towards the longitudinal center of the cylindrical mesh such that the proximal end is moved distally and the distal end is moved proximally, as follows.

Fig. 9 shows a sectional elevation view of the mesh of Fig. 1 in a first position wherein distal end 14 has been pulled partially through the center of the cylindrical mesh 10 such that distal end 14 is received within the central body portion of mesh 10. Thereafter, as shown in Fig. 10, proximal end 12 is then pushed partially through the center of the cylindrical mesh 10 such that proximal end 12 is also received within the central body portion of mesh 10.

In the aspect of the invention shown in Figs. 9 and 10, mesh 10 will especially tend to expand radially at outer surface 11 and inner surface 13 close to ends 12 and 14 as shown. Expansion of mesh 10 in these regions will cause formation of bulges immediately outside of the distal and proximal ends of hole 21 as shown. Such bulges will tend to anchor the mesh such that it does not move longitudinally in hole 21. In the aspect of the invention shown in Figs. 9 and 10, both proximal end 12 and distal end 14 may optionally be covered by mesh or end caps since these ends need not pass through one another.

In this and the above discussed aspects of the invention, outward radial forces of the portions of the mesh which are curled within the main body of the mesh will preferably

act against the outside walls of the outer tube creating frictional loads along the longitudinal axis that far exceed the unfolding tendency of the mesh.

A further advantage of the present invention is that it may be adapted to compensate for both thick or thin annular walls. For example, should the length of hole 21 be slightly longer than the length of mesh 10, ends 12 and 14 will still be fully engaged within hole 21. Another advantage of the present invention is that the exposed portions of the mesh projecting out of hole 21 (e.g.: bulges 15 and 17) will be atraumatic, minimizing any potential irritation due to tissue contact due to the soft and flexible nature of the mesh.

An alternate aspect of the first embodiment of the present invention is shown in Figs. 11 to 12B, as follows. A mesh 50, (similar in characteristics to mesh 10 as described above), is provided. As seen in the cross sectional view of Fig. 12A, a suture/tether 52 runs from distal end 54 through the center of installation tube 60. As mesh 50 is advanced distally into hole 21, as shown in Fig. 12B, it will form a "reversing funnel" shape with the outer edges of mesh 50 wrapping over the body of the mesh inserted therethrough.

Figs. 13A and 13B show respective front and side views of a second design of the present invention in which device 100 comprises a generally planar sheet of material which is cut or formed in a circular shape, having a plurality of radially extending "flower petal" extensions 102. These devices allow pressure equalization through the venting of lower viscosity fluids but retain higher viscosity fluids and solids.

When inserted into a surgical access hole, petals 102 are first flexed radially inward in direction I. Accordingly, sheet 100 assumes a generally conical shape when inserted into hole 21 in intervertebral disc 20, as is shown in Fig. 14. After device 100 has been positioned in hole 21, (for example with a rod), petals 102 are released. Accordingly, petals 102 will tend to "spring back", moving radially outwards in direction O such that petals 102 will press against the outer surfaces 22 of hole 21 thereby anchoring device 100 in position in hole 21. As such, petals 102 act as cantilever leaf springs anchoring device 100 in position in hole 21, thereby resisting outward (i.e. proximal) loading due to extruding nucleus pulposus.

As is shown in Fig. 15, optional barbs 104 may also be provided at the distal ends of petals 102 to assist in anchoring petals 102 of device 100 against walls 22 of hole 21. Fig. 15 shows a variety of alternate designs with differently shaped petals 102. Fig. 15 also shows an optional design for a sheet 120 which does not have petals. Rather, such a sheet is preferably crimped into a conical shape such that it can be positioned in hole 21. Thereafter sheet 102 will expand (ie: flatten itself) to seal hole 21 with holes 121 allowing for fluid

movement similar to the movement permitted between adjacent petals 102 as shown in other aspects of the invention.

Device 100 may preferably by formed to accommodate hole 21 having an inner diameter ranging from one-half to three quarters of the disc diameter in its free and flattened state. Device 100 can be formed from wire or molded from plastic.

In preferred aspects, a plurality of devices 100 can be inserted into hole 21 in sequence as shown in Fig. 16. Such an arrangement has the advantage of further restricting the movement of nucleus pulposus out of the center of disc 20. Fig. 17 corresponds to Fig. 16 but with the apexes 101 of devices 100a and 100b pointing in opposite directions.

Figs. 18, 19 and 20 show successive steps in a method of inserting oppositely facing interlocking devices 100. Referring to Fig. 18, discs 100a and 100b are first introduced into hole 21 (not shown) in an orientation such that their apexes 101a and 101b are pointing in opposite directions. A positioning rod 120 is used to push devices 100a and 100b together such that devices 100a and 100b become inverted such that their apexes 101a and 101b will be pushed together. As is seen in Fig. 20, apexes 101a and 101b can comprise interlocking features such that they can be assembled to interlock together thereby forming a solid structure which tends to reduce radial movement of the respective apexes.

Experimentally Developed Embodiments:

The Applicants of the present invention have succeeded in constructing various experimental embodiments of the present invention, as follows. These experimental embodiments are meant to illustrate various exemplary systems in accordance with the present invention. The present invention is not limited to the experimental embodiments described herebelow. Rather, any suitable system for achieving the structures and methods of the present invention as claimed is considered within the scope of the present invention.

Mesh 10 of the present invention was experimentally constructed as a braided tube approximately 3 mm in diameter when in the relaxed state, and at least 9 mm in diameter when expanded. This tube was be braided from 24 individual strands of .15 mm polypropylene suture. Alternatively, however, various numbers of strands may employed in the braiding of the tube.

An experimental embodiment of mesh 10 was constructed from a 45 mm length of braid which is cut and then placed over a heat resistant mandrel that just fits inside of the braid. The mandrel may preferably be fabricated from a machineable ceramic. A 12 mm long stainless steel tube whose inside diameter just fits over the braid may be placed over

the braid/mandrel assembly with approximately 1 mm of braid exposed over the mandrel. The braid/mandrel/tube assembly was then placed in a lathe chuck or other machine capable rotating the assembly about it's longitudinal axis in a controlled manner. The end of the braid was then radiantly heated to just past the melting point of the braid polymer. The braid end was reformed to create a semi-rigid ring with in inside diameter of approximately equal to the original inside diameter of the braid. By using this non contact method of forming using radiant heat and the fluidic surface tension of the re-flowing polymer, a robust and smooth unitary ring was quickly formed. The whole assembly was then removed from the rotating machinery. The first mandrel was removed from the assembly and a second forming mandrel was inserted in it's place. The second forming mandrel was made of a machineable ceramic material, and one end of the mandrel being formed with a tapered bullet shaped tip. The bullet tip was placed even with the tapered tip at the end of the proximal end of the braid. The 12 mm long stainless steel tube was then placed over the braid/mandrel assembly with approximately 1 mm of braid exposed over the bullet tipped mandrel. The braid/mandrel/tube assembly was again placed in the rotating machinery and slowly rotated about it's longitudinal axis. The proximal end of the braid was then radiantly re-flowed to form a semi-rigid ring with an inside diameter of approximately one half to one quarter of the original braided diameter. The forming process described above can be accomplished in many different ways using a variety of equipment and techniques. Alternatively, rings of non-native material may have instead been secondarily added to the braided tube. The braid was then removed from the forming tools. A long piece of suture was then transversely passed through at least one braid intersection located near the distal end of the device. The tag ends of the suture are then brought together to form a loop with the device near the approximate center of the suture. This loop forming procedure is repeated twice more to form a system of three equally spaced suture loops with a radial spacing of about 120° when viewed from the end. The braid/loop assembly was then placed at the distal end of a long rod or tube whose outside diameter will allow for the longitudinal urging of the proximal end of the device and still allow for diametral clearance of at least two wall thickness of the braid material. The loops of suture were placed along side the length of the urging rod and arranged in a manner to prevent tangling of the tag ends. A second long hollow tube with an outside diameter that allows for passage into the surgical defect and inside diameter that allows for a slight diametral compression of the braid/loop assembly, is passed over the braid/loop assembly until approximately 4 mm of braid is exposed. It is to be understood that appropriate handles,

grips and controls may also be added to the installation tool to enhance placement of the device and ease of use.

WHAT IS CLAIMED IS:

1. A method of sealing a hole in a body part, comprising:

introducing a generally cylindrical shaped mesh into the hole; and

moving at least one end of the cylindrical shaped mesh at least partially through an interior portion of the cylindrical shaped mesh such that the mesh expands radially outwards against sides of the hole.

2. The method of claim 1, wherein moving at least one end of the cylindrical shaped mesh at least partially through an interior portion of the cylindrical shaped mesh comprises:

advancing a proximal end of the mesh in a distal direction.

3. The method of claim 2, wherein the proximal end is advanced in a distal direction by a push rod.

4. The method of claim 2, wherein the proximal end is advanced distally past the distal end.

5. The method of claim 2, wherein the mesh bulges around the perimeter of the proximal end of the hole.

6. The method of claim 1, wherein moving at least one end of the cylindrical shaped mesh at least partially through an interior portion of the cylindrical shaped mesh comprises:

advancing a distal end of the mesh in a proximal direction.

7. The method of claim 6 wherein the distal end is advanced proximally past the proximal end.

8. The method of claim 6, wherein the mesh bulges around the perimeter of the distal end of the hole.

9. The method of claim 6, wherein the distal end is advanced in a proximal direction by pulling on a tether attached to the distal end of the mesh.

10. The method of claim 1, wherein the body part is a bony structure.

11. The method of claim 10, wherein the body part is a vertebral annulus.

12. The method of claim 1, wherein the cylindrical shaped mesh is introduced into the hole by:

inserting a tubular inserter into the hole, wherein the mesh is received within a central bore of the tubular inserter; and

withdrawing the tubular inserter from the hole while holding the mesh in the hole.

13. The method of claim 12, further comprising:

pushing the proximal end of the mesh in a distal direction with a cylindrical inserter received within the tubular inserter.

14. A method of sealing a hole in a body, comprising:

introducing a generally cylindrically shaped mesh into the hole; and

pushing a proximal end of the cylindrically shaped mesh at least partially through itself.

15. A method of sealing a hole in a body, comprising:

introducing a cylindrically shaped mesh into the hole; and

pulling a distal end of the cylindrically shaped mesh at least partially back through itself.

16. A device for sealing a hole in a body, comprising:

a generally cylindrical mesh formed from a plurality of helical strands.

17. The device of claim 16, wherein the helical strands are formed from suture material.

18. The device of claim 16, wherein the mesh comprises a flexible tube of interwoven springs.

19. The device of claim 16, wherein at least one of the proximal and distal ends of the cylindrically shaped mesh are covered by an end cap.

20. The device of claim 19, wherein the end cap is made of mesh.

21. The device of claim 16, wherein,

at least one end of the cylindrical mesh comprises a non-expandable circular ring.

22. The device of claim 21, wherein,

both the distal and proximal ends of the mesh comprise non-expandable circular rings, wherein the diameter of the one end is smaller than the diameter of the other end.

23. The device of claim 24, wherein,

the diameter of the proximal end is slightly smaller than the diameter of the distal end such that the proximal end can be snap-fit through the distal end.

24. The device of claim 16, further comprising:

a plurality of suture-tethers connected to the distal end.

25. The device of claim 16, wherein the mesh has a diameter of approximately 1 to 8 millimeters.

26. The device of claim 25, wherein the mesh has a diameter of approximately 3 millimeters.

27. The device of claim 16, wherein the helical strands are made of polypropylene.

28. The device of claim 16, wherein the helical strands have individual diameters of approximately 0.15 millimeters.

29. The device of claim 16, wherein the distal end is tapered.

30. A device for sealing a hole in a body, comprising:

a sheet-like structure comprising a plurality of radially extending petals, the petals being adapted to flex radially outwards when bent inwards into a generally conical shape.

31. The device of claim 30, further comprising:

a barb disposed on the distal end of each of the petals.

32. The device of claim 30, wherein the petals tend to spring radially outwards such that the structure tends to assume a planar form.

33. A method of sealing a surgically formed hole in a body, comprising:

inwardly bending a plurality of petals extending from a generally planar sheet of material, such that the sheet of material assumes a conical shape;

introducing the structure into the hole;

allowing the bent petals to spring radially outwardly, such that the petals of the structure push against the walls of the hole, thereby anchoring the structure in the hole.

34. The method of claim 30, wherein the structure is inserted into the hole with the petals angled in a proximal direction.

35. A method for sealing a hole in a body, comprising:

inserting a plurality of sheet-like structures into the hole, each comprising a plurality of radially extending petals, the petals being adapted to flex radially outwards when bent inwards into a generally conical shape.

36. The method of claim 35, wherein two structures are inserted into the hole with their respective apexes facing towards one another.

37. The method of claim 36, wherein the two apexes further each comprise an interlocking portion such that the two structures are interlocked together.

38. The method of claim 35, wherein each of the two structures are initially inserted with their apexes pointing away from one another.

FIG 1

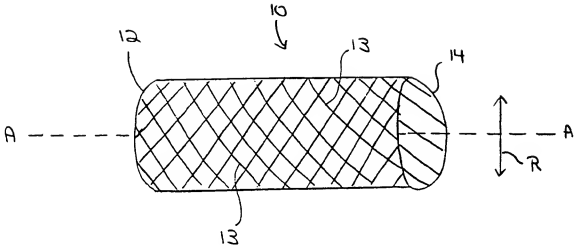


FIG 2

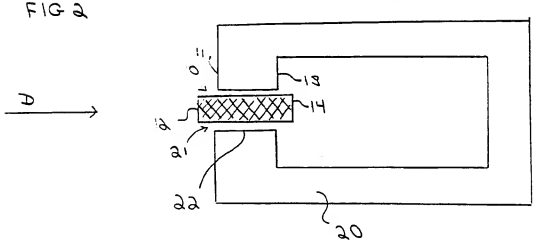


FIG 3

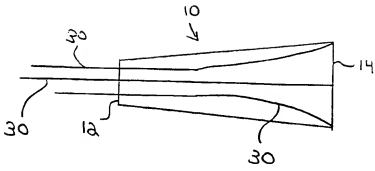


FIG 4

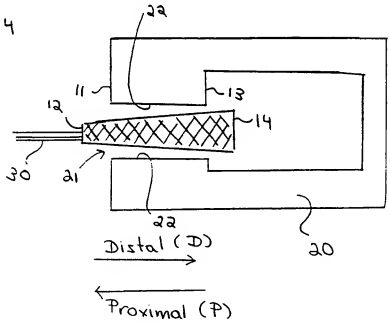


FIG5

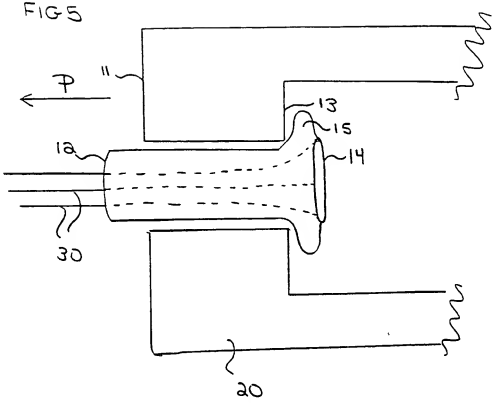


FIG6

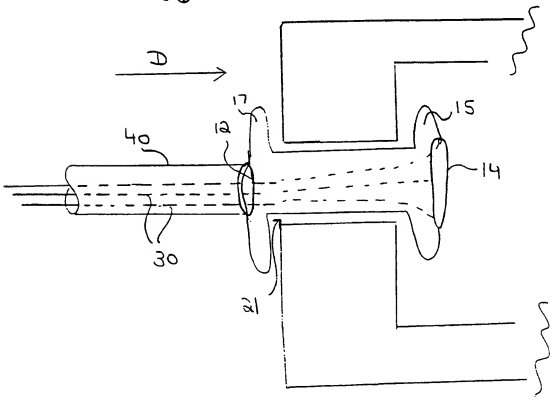


FIG 7

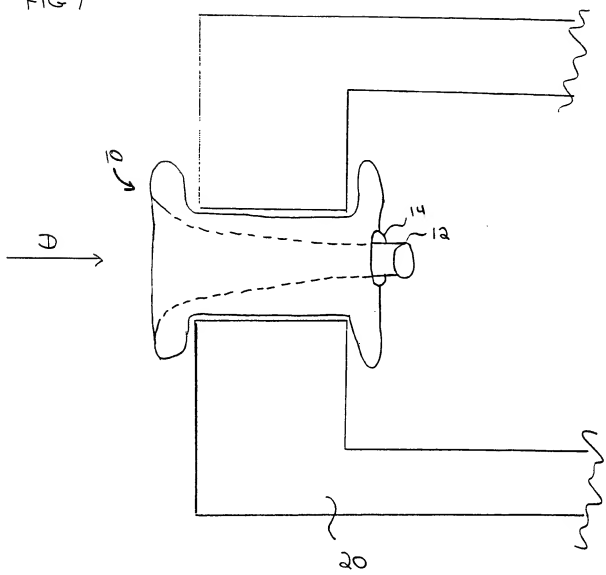


FIG 8

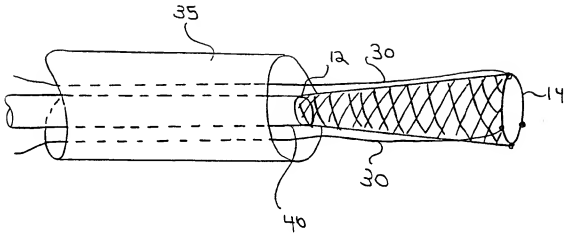


FIG 9

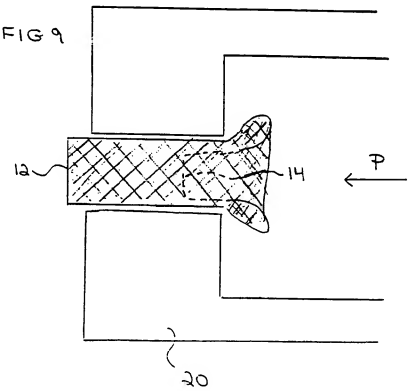


FIG 10

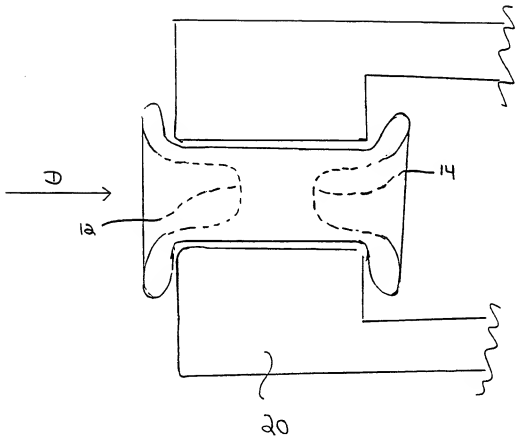


FIG 11

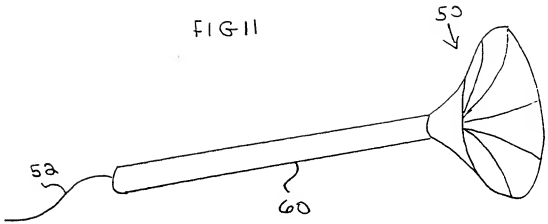


FIG 12A

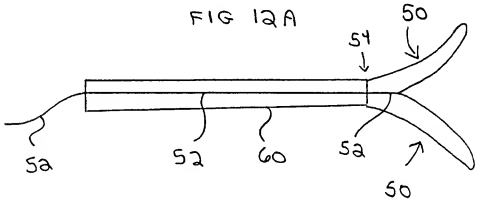


FIG 12B

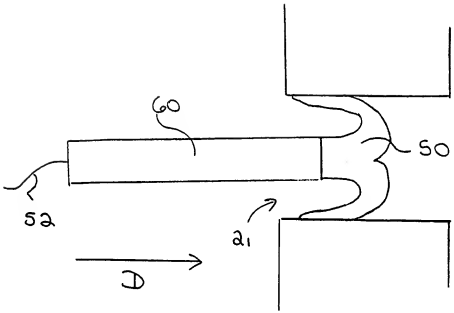


FIG 13A

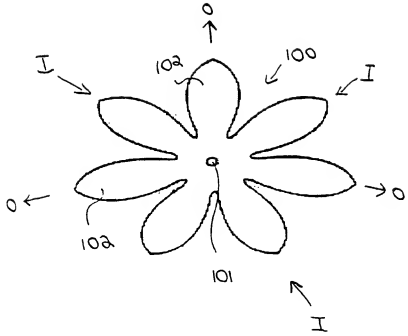


FIG 13B

FIG 14

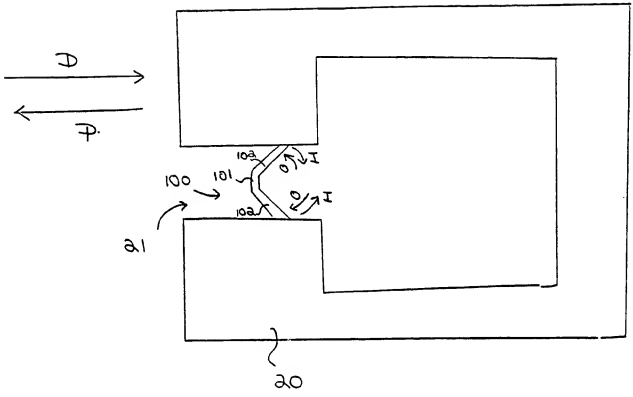
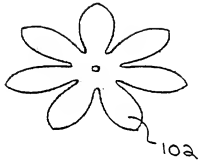
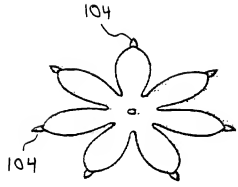
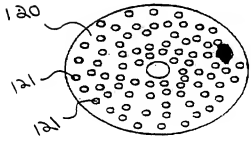
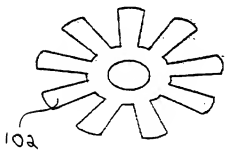


FIG 15









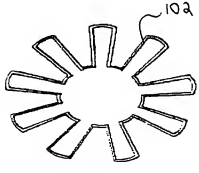


FIG 16

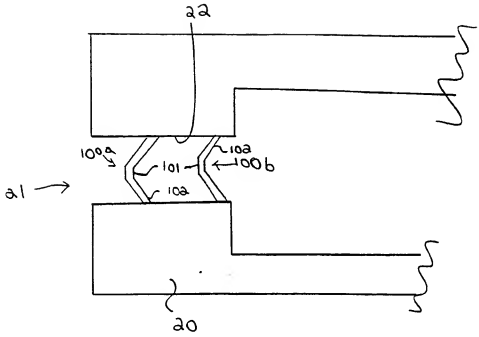
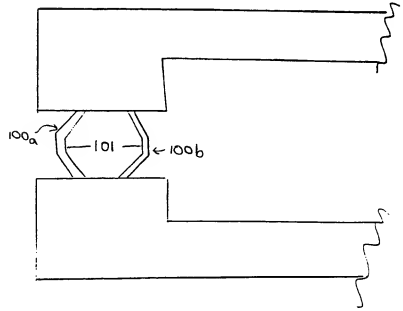


FIG 17



Distal (D)

Proximal (P)

FIG 18

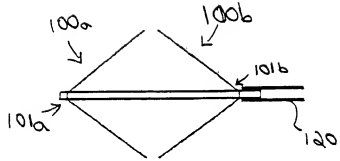


FIG 19

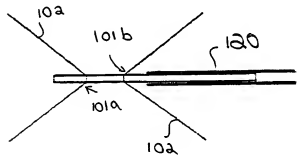
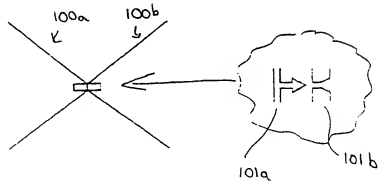


FIG20



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/25678

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61M 29/00
US CL : 606/200
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/200, 151, 157, 158, 191

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,674,241 A (BLEY et al.) 07 October 1997, figs.1-3.	1-29
X --- Y	US 5,846,261 A (KOTULA et al.) 08 December 1998, figs.1-32.	1-29
X	US 5,133,733 A (RASMUSSEN et al.) 28 July 1992, figs.1 and 2.	30-38
X,P --- Y,P	US 6,036,720 A (ABRAMS et al.) 14 March 2000, figs. 1 and 3.	30-38

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	documents published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 05 DECEMBER 2000	Date of mailing of the international search report 12 JAN 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LIEN NGO Telephone No. (703) 305-0294

Form PCT/ISA/210 (second sheet) (July 1998)*

THE USE OF METHYLMETHACRYLATE IN THE TREATMENT OF GIANT CELL TUMOURS OF THE PROXIMAL TIBIA

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Auckland

Two cases of giant cell tumour of the proximal tibia are presented where the defect remaining after curettage has been filled with methylmethacrylate bone cement. The problems associated with the present management of giant cell tumours and the potential advantages of using methylmethacrylate are discussed.

THE primary management of the majority of giant cell tumours presents a difficult problem. The tumours are rare, occasionally malignant lesions, but with a high local recurrence rate. An initial biopsy and the subsequent histological grading do not significantly help to predict the aggression and potential recurrence of the tumour (McGrath, 1972; Murphy and Ackerman, 1956). Complete resection without significant loss of function may be possible for some giant cell tumours and may be indicated for tumour recurrence or overt malignancy, but for the majority which occur in the epiphyses of the femur and tibia adjacent to the knee joint such radical primary treatment is seldom justified.

The most commonly accepted primary treatment is curettage of the tumour and its cavity associated with cancellous bone grafting. This procedure is necessarily followed by a long period of protection of the adjacent joint during incorporation of the bone graft. Curettage obliteration of the cavity with polymethylmethacrylate bone cement is suggested as a means of primary treatment which allows rapid recovery of joint function.

CLINICAL RECORDS

CASE 1.— A 31-year-old woman developed pain over the lateral aspect of the right proximal tibia ten months prior to presentation. This was attributed by the patient to a twisting injuring when alighting from a bus. She complained of an intermittent dull aching in the area of the right knee, with no other local, joint or systemic symptoms. Examination revealed a fullness on the lateral side of the right proximal tibia, with increased local temperature and tenderness on firm palpation.

Radiographs of the right knee showed a large radiolucent lesion in the lateral tibial condyle, and there appeared to be breaching of the cortex Figure 1, left. A skeletal survey was negative, and a full blood screen was normal except for an ESR of 27 mm in one hour.

Surgery was performed seven days after presentation. Through a longitudinal incision the cortex of the proximal tibia was found to be thin, with areas of erosion but no breaching of the periosteum. A window was cut in the bone, and a specimen of tumour sent for immediate histological examination showed a giant cell tumour Grade 2-3 (Jaffe, *et al*, 1940). The lesion was curetted, with the removal of all involved cortex and adjacent cyst wall. The undersurface of the articular cartilage was exposed on one area, but the remaining area was covered by a thin plate of subchondral bone. The defect was then filled with methylmethacrylate bone cement, and it appeared that good support of the lateral condyle had been achieved. No external splintage was applied after surgery (Figure 1, centre).

The postoperative period was uneventful, and the patient was mobilized well enough with a walking stick to be discharged from hospital on the third day after operation. Within six weeks of surgery she was walking painlessly without assistance and had regained a full range of knee movement (Figure 1, right).

In the ensuring follow-up period of 36 months she has remained asymtomatic, with no radiological evidence of recurrence.

CASE 2.— A nurse aged 19 years presented with a six months' history of pain over the medial aspect of the left knee. There was no suggestion of precipitating treume. She had been otherwise well, but had lost six kilograms in weight over the previous 12 months. Examination revealed no abnormality except for some tenderness over the anteromedial aspect of the left proximal tibia.

Radiographs showed a lytic lesion in the medial tibial condyle, with a suggestion of breaching of the cortex (Figure 2, left), but this could not be confirmed on tomography. A skeletal survey and full blood screen were normal.

She was admitted to hospital for surgery six days after presentation. Through a curved incision over the medial tibial condyle the periosteum was found to be intact, the cortical bone being paper-thin and easily indented. Large amounts of gelatinous bloodstained tumour sent for immediate histological examination showed a giant cell tumour, Grade 2. The tumour was removed by curettage and there appeared to be no defect in the subchondal bone. The walls of the cavity were then freshened, using a high speed dental burr e

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[2] Associate Professor of Orthopaedics, University of Auckland, Auckland, New Zealand.

Reprints: Dr S. Baddeley, Flat 20, 16 Gladstone Rd, Parnell, Auckland, New Zealand.

FIGURE 1: Case 1, (left) anteroposterior radiograph of the affected knee showing eccentric osteolytic lesion in the lateral tibial condyle. Note the breach in the cortex; (centre) radiograph taken after surgery showing, extent of cavity filled with radiopaque methylmethacrylate, (right) the affected knee 16 months after surgery — a full, painless range of movement.

irrigation. The cavity was then filled with methylmethacrylate bone cement and good support of the medial condyle was achieved. Following surgery a plaster backslab was applied.

Postoperative radiographs (Figure 2, centre) showed the cavity to be biloculated and involving two-thirds of the diameter of the proximal tibia. Methylmethacrylate appeared to be impinging directly on to the articular cartilage of the medial tibial plateau.

Mobilization was commenced immediately, and the patient was discharged from hospital on the fourth day after operation, walking well with crutches. Her post operative course was complicated by two haemarthroses, the first four weeks and the second ten weeks after surgery. Both required admission to hospital and aspiration. By the 14th postoperative week she had regained a full range of knee movement (Figure 2, right) and was asymptomatic.

In the follow-up period of 32 months she has remained symptom-free, with no radiological evidence of recurrence.

DISCUSSION

The currently accepted treatment of giant cell tumour of bone by curettage and bone grafting, or resection where appropriate, presents several problems for the orthopaedic surgeon. These are: (i) the continuing high rate of local recurrence; (ii) the frequent need for very large cancellous bone grafts; (iii) the loss of function of the adjacent joint, secondary to either articular cartilage damage, during surgery or the prolonged immobilization necessary following bone grafting; and (iv) the difficulty of making a radiological diagnosis of recurrence in or about a heterogenous bone graft.

It is believed that the use of methylmethacrylate bone cement in filling large defects may help to solve these problems. The curing temperature of methylmethacrylate may reach as high as 90°C at the bone-cement interface under conditions where the cooling effect of the circulation is removed by use of a tourniquet (as would be the case in surgery about the knee), and where there is a large bulk of methylmethacrylate (Feith, 1975). Temperatures of this magnitude have been shown to be lethal to adjacent cells, and in this way the use of methylmethacrylate provides the possible advantage of thermal cautery to the whole cavity. It is hoped that this will result in a decrease in the rate of recurrence.

FIGURE 2: Case 2, (left) anteroposterior radiograph of affected knee; (centre) radiograph taken after surgery, showing the extent of the bilocular cavity, with methylmethacrylate apparently extending to the articular cartilage; (right) the effected knee 14 months after surgery — a full painless range of movement.

The use of methylmethacrylate to fill any sized cavity obviates the problems associated with acquiring large quantities of cancellous bone or the use of homograft bone.

In the treatment of tumours that have destroyed articular cartilage, or where articular cartilage has been sacrificed to gain adequate resection of tumour, the use of methylmethacrylate can be augmented with prosthetic replacement of the articular surface, and it is believed that this will have special application to those tumours about the knee and proximal femur. Early mobilization and weight bearing were possible in our patients with the use of methylmethacrylate, and the return of excellent joint function can be expected.

The radiological appearance of a defect filled with methylmethacrylate with added barium is that of a homogenous mass with easily defined borders. It is hoped that this will aid in the early radiological diagnosis of recurrence.

We do not recommend that this form of treatment be applied to all giant cell tumours. We believe that it should be considered for those tumours in which resection is not possible without amputation or loss of limb function, and in those giant cell tumours where there has been no gross breach of the cortex and involvement of the soft tissues.

REFERENCE

FEITH, R. (1975). *Acta. orthop. scand.*, Suppl. No. 161: 14.

JAFFE, H. L., LICHENSTEIN, L. and PORTIA, R. B. (1940). *Arch. Path.*, 30: 993.

MCGRATH, P. J. (1972). *J. Bone Jt Surg.*, 54B: 216.

MURPHY, W. R. and ACKERMAN, L. V. (1956). *Cancer (Philad.)*, 9: 317.

A SIMPLIFIED SURGICAL APPROACH FOR LUMBAR DISC EXCISION

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Department of Orthopaedics and Traumatic Surgery, Royal North Shore Hospital, and The University of Sydney

A simple surgical approach to the distal lumbar spine for disc excision is described and the relevant surgical anatomy reviewed. The approach is considered to have many advantages over formal laminectomy for the same purpose in the majority of cases. The indications and contraindications for its use are discussed.

THE natural history of lumbar disc prolapse is one of recurrent attacks of low back pain with or without sciatica, while between episodes the patient may be quite asymptomatic. Indeed, in any given attack, the likelihood of spontaneous remission is high, and this probability should influence management accordingly. Nevertheless, disc excision, when indicated, provides prompt and gratifying relief of symptoms, though the long-term results of operative and non-operative treatment, excluding the rare occurrence of acute, profound neurological deficit, are little different from each other.

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[2]M. D. Ryan, Senior Lecturer in Surgery (Orthopaedics and Traumatic Surgery), Royal North Shore Hospital, St Leonards, N.S.W. 2065.

Reprint requests to Professor T. K. F. Taylor, Department of Orthopaedics and Traumatic Surgery, Royal North Shore Hospital, St Leonards, N.W.S. 2065.

Laminectomy is the term widely applied to the operative procedure for disc excision, and this is firmly linked with neurosurgical traditions. The surgical access to the spinal canal and its contents has always tacitly implied laminectomy of varying extent, and with tumours, for example, one can present no logical argument to the contrary. The removal of a lumbar disc prolapse is a quite different matter in the vast majority of patients who come to operative treatment. Here it amounts to little more than retrieval of the loose body, the disc sequestrum, and the removal of the readily accessible degenerated disc tissue from the offending intervertebral space. In this regard, it can be compared reasonably with arthrotomy for a loose body, and spondylotomy might well be a suitable and more correct alternative term for the procedure.

The purpose of the present paper is to describe a simplified surgical approach for lumbar disc

N. Godoli, A. Guerra, R. Lanfranchi, F. Sabetta, G. Soncini: Treatment of Tibial Plateau Fractures
Chir. Org. Mov. 72(3):235-236; 247-256, [date not given].

[Editor's note: The copy of the cover of the journal provided indicates Vol. LXII, whereas the text to be translated indicates Vol. LXXII.]

Job No.: 6572-91838
Translated from Italian by the Ralph McElroy Translation Company
910 West Avenue, Austin, Texas 78701 USA

TREATMENT OF TIBIAL PLATEAU FRACTURES

Introduction

For many years, the treatment of tibial plateau fractures has divided orthopedic specialists into two opposing camps: proponents of orthopedic treatment and proponents of surgical treatment.

Unfortunately, we do not have a reliable statistical comparison between the results of invasive and conservative treatment, even among practitioners who may have ample statistics, as we do. In reality, the different types of treatment do not offer comparable data, because choice of treatment is often based on personal criteria, sometimes debatable and sometimes perfectly justified, and the material is clearly different in the two groups.

Those who oppose surgical intervention maintain that an examination of long-term results shows that, in tibial plateau fractures, there is a relatively large margin of accommodation. For example, when sinkage is not too extensive, the femoral condyle does not become locked into the depression, but is supported by the intact surrounding part. Or if the articular surface of the tibia is expanded, the overall support plane for the femoral condyles may still permit normal orientation with respect to the longitudinal axis of the tibia.

This adaptability can probably be explained in part by the fact that, in the knee, there is not a perfect fit as there is between the femoral head and the acetabulum, partly because the menisci and the fibrous scar tissue covering the fracture site contribute to maintaining the normal height and the uniformity of the plateau.

On the other hand, those in favor of surgical intervention believe that, in treating joint fractures, the functional result is directly related to the degree of anatomical reduction, and it does not seem logical that the standards for all joint fractures (anatomical reduction as a necessary condition for an optimal functional result) should not also be the standard for fractures of the tibial plateau.

This is particularly true if we consider that the knee is a weight-bearing joint in which the passage of time makes all the anatomical deficiencies intolerable – sinking, axial deviations, joint loosening – that in theory may not give rise to severe functional disorders, but with the passage of time are expressed as complications of arthritis. However, in recent years we have seen a more balanced approach, and the most notable studies are increasingly inclined toward surgical solutions because of improvements in materials and in osteosynthesis techniques.

Therefore, the controversy between proponents of orthopedic treatment and surgical osteosynthesis has been resolved.

* * *

Part II
SURGICAL TREATMENT OF MONOCONDYLAR FRACTURES OF THE TIBIAL PLATEAU

The AA. report on the results in 98 cases of fracture of one tibia condyle, surgically treated with elevation of the fractured bone, filling of the empty space with homologous bone transplants, and fastening with screws. The operation is usually performed without opening the joint.

Monocondylar fractures represent the most common occurrence of traumatic injuries of the proximal epiphysis of the tibia.

In our opinion these injuries, which are well understood from an etiopathogenic and anatomopathological standpoint, require surgical treatment, with the exception of the few cases in which there is no breakup of the fracture site.

In fact, with nonsurgical means, it is not possible to obtain even an acceptable reduction, indispensable for a favorable result, when dealing with joint fractures.

Even modest breakup of a tibial condyle may alter the joint axis, and over time may cause arthritic degeneration of the joint ends. Therefore, surgery is the only means to avoid or at least delay the appearance of this complication.

Classification

As already indicated in Part I, we have classified the various types of monocondylar tibial fractures as follows:

A) External condylar fractures:

Type 1: Pure linear fracture

Type 2: Fracture with pure sinkage

Type 3: Linear fracture with sinkage, or mixed

B) Internal condylar fractures:

Type 1: Linear fracture

Type 2: Fracture with sinkage

In the external condyle, the most frequent location of these injuries, we find that linear fractures follow the system of the external trabecular fasciculi. In most cases, the fracture involves about one-third of the plateau. Displacement is usually modest.

In pure sinkage, the total sinking of a hemiplateau is often associated with fibula head fracture.

Another variety is the one with anterior sinkage, while the variety with central sinkage in Hülten's hollow is very rare. The mixed forms are most frequent. These are characterized by a vertical fissure that detaches a fragment at a right angle from the more peripheral part of the plateau and by sinkage of its remaining surface.

We also distinguish an anterior variety that is the most frequent, a posterior variety which is rare, and a total variety which, although exceptional, should be mentioned because of its gravity.

At the internal condyle we find the pure linear variety, which corresponds to the external linear fracture, although it is much more rare.

In the variety with sinkage, the form with total sinkage is prevalent, and is the cause of severe varus deformities, while marginal impactions are rare.

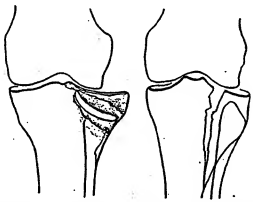


Figure 1. Diagram showing the two fundamental types of monocondylar injuries: linear type on the right, type with sinkage on the left.

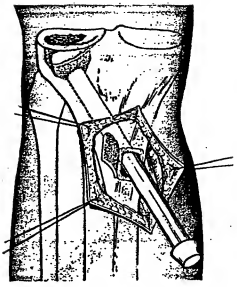


Figure 2. Surgical technique. Step 1: Controlateral cutaneous incision, preparation of the window in the cortex, elevation of the plateau with beater under amplioscopic control.

Indications

In our opinion, indications for surgery in monocondylar fracture of the tibia are as follows:

1) Linear fractures with breakup of the fragments (expansion of the plateau): reduction with Barr screws or screws in the spongiosa.

2) Fracture with impaction of more than 3 mm: elevation of the cartilaginous plane, packing the residual cavity with small scraps of homoplastic spongy bone, without arthrotomy.

3) Mixed fracture: reduction of the fracture, synthesis with Barr screws or screws in the spongy layer, and packing of the cavity with homoplastic bone without arthrotomy.

We use screws in the spongy layer or Barr screws since, in addition to containing the focus, they also constrain it, thereby reducing expansion of the plateau.

In the pure linear form, screws are applied simply to confine the fragments of the fracture, while in the mixed type, they act to provide a certain measure of support to the zone of the elevated plateau.

Transplanting of spongy bone has the purpose of filling the space resulting from compression of the metaphyseal trabeculae, permitting more rapid and complete consolidation of the fracture site and sound support, until the first phases of healing, for the zones of joint cartilage inserted in situ.

Insofar as possible we avoid arthrotomy because we want to minimize damage to the joint, and because the technique used is capable, in most cases, of providing satisfactory alignment of the fracture.

However, considering that the factor with the most influence on the result is reconstruction of normal anatomy, we do resort to arthrotomy when elevation by extraarticular means does not seem sufficient.

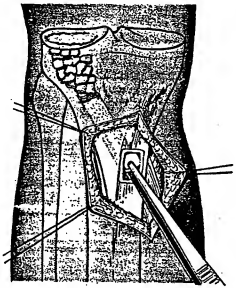


Figure 3. Surgical technique. Step 2: Bone loss is repaired with large pieces* of homoplastic spongy tissue, generally from the femoral epiphysis.

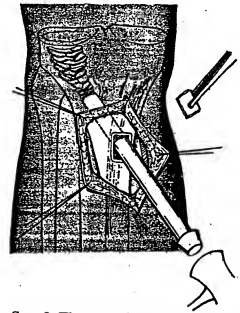


Figure 4. Surgical technique. Step 3: The transplants are packed with the beater to form a sound support for the cartilaginous plateau.

* [Translator's note: literally "bracts"]

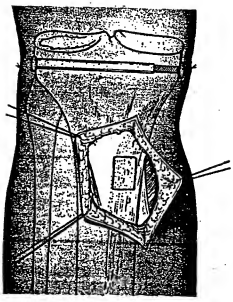


Figure 5. Surgical technique. Step 4: The cortical fragment is re-applied in situ, and the Barr screw is applied with two other short incisions.

Figure 6. 70-year old patient. Linear fracture. Screw attachment with Barr screws. Clinical and radiographic results are good three years after removal of the screw. These are the fractures with the highest percentage of favorable results in relation to the lesser gravity of the injury to the joint cartilage.

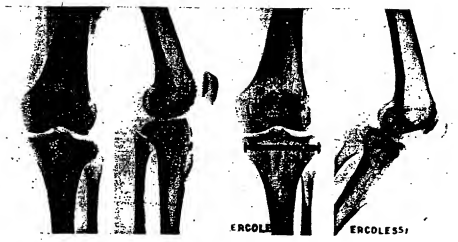


Figure 7. 28-year old patient. Fracture with pure sinking. Elevation, packing, and Barr screws. Clinical and radiological results are excellent after 5 years.

Surgical technique

Although similar in its fundamentals, the surgical method varies depending on the type of fracture.

Linear fractures

In linear fractures, after reduction by traction with a transskeletal wire and manual maneuvers in varus and valgus direction under radiographic control, we make two small linear incisions corresponding to the internal and external plateau. Then, from an extraarticular position we perforate the tibial mass and install the Barr's screw with an appropriate screw holder and screw it in until the diastasis is completely reduced.

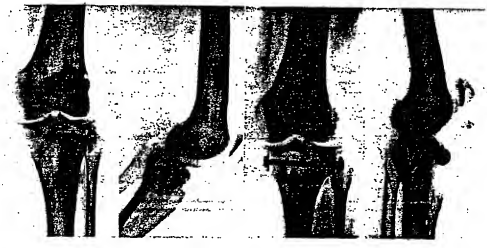


Figure 8. 60-year old patient. Mixed fracture. Elevation, packing, Barr screws. Clinical and radiological results are excellent one year later.

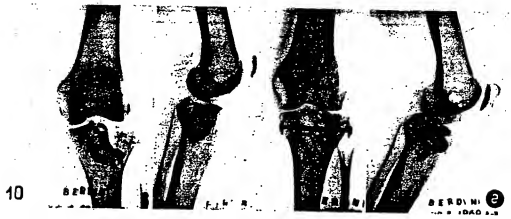


Figure 9. 34-year old patient. Fracture with sinking. Elevation, packing, Barr screw. Good clinical and radiographic results. Even in the presence of significant sinking, we were able to obtain good correction without arthrotomy.

Fractures of the mixed type and by sinkage

For elevation of the external tibial plateau, which is the most frequent case, the cutaneous incision is made on the medial side.

This incision begins about 10 cm below the joint space, and is 4-5 cm long.

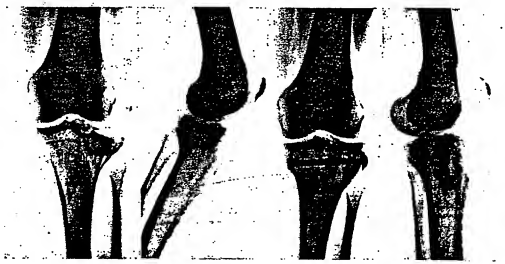


Figure 10. 31-year old patient. Mixed fracture. Elevation, packing, Barr screw. Good clinical and radiological results after one year.

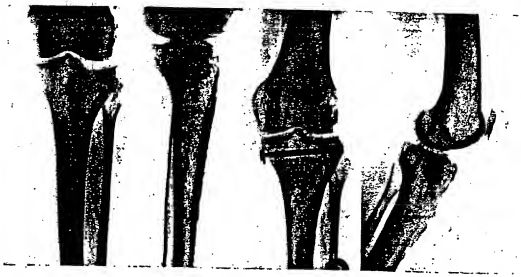


Figure 11. 51-year old patient. Mixed fracture. Elevation, packing, and Barr screw. Good clinical and radiological results after 3 years.

When the superficial fascia is cut open, the periostium is detached, skeletonizing a small surface of the tibial metadiaphysis, and there we make a quadrangular operculum with a side of 1.5 cm.

Through this we introduce a beater [unconfirmed translation] into the epiphysis and, under amplioscopic control, we elevate the hemiplateau (Figure 2). The fragment is then held in situ by introduction, into the cavity remaining from compression of the trabeculae, of small pieces (Figure 3) of homoplastic spongy bone from the bank, taking care to pack them with the reamer to create a solid support on the cartilaginous plateau (Figure 4).

The bone plug is then put back in place and the surface layers are sutured.

Then, if necessary, a Barr screw is applied as described above (Figure 5).

A plaster cast is then applied with the knee flexed 15–20°.

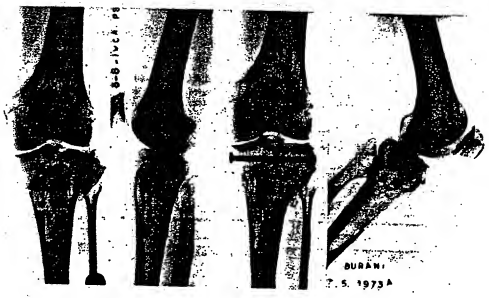


Figure 12. 56-year old patient. Bicondylar fracture of the 2nd type with very little breakup. Good clinical and radiological results after 5 years. We are at the limit of the indication for osteosynthesis with a simple Barr screw.

Postoperative treatment

The plaster cast (knee to foot) is kept on for 30 days. After it is removed, the patient has a physical therapy cycle that excludes heat and that uses essentially electrotherapy and active rehabilitation.

When spongy bone is fractured, direct weight bearing is permitted only after 2 months, and during this period the patient can walk with two underarm crutches to keep the weight off the injured leg.

Casuistics

Between 1965 and 1972, we performed surgery on 98 monocondylar fractures.

Distribution by sex was as follows: 52 males, 46 females.

The right side was injured in 28 cases and the left in 68 cases. There were 2 cases of bilateral fracture.

Distribution by age decades is shown in the table that follows.

Table 1

(1) Decenni	2°	3°	4°	5°	6°	7°	8°	9°
(2) N. casi	2	4	20	18	28	19	6	1

Key: 1 Decades
2 No. of cases

As shown by this table, the age most affected was adults in the 4th to 6th decades. For the external condyle, associated injuries were most frequently: fracture of the fibular head, observed in 12 cases, and fracture of the leg, observed in 4 cases.

We observed the following associations:

Tibiotarsal fracture: 2 cases; fracture of the acetabulum, 2 cases; injury to the medial collateral ligament, 2 cases.

There was one case each of fractured ribs, heel, maxilla, neck of the humerus, clavicle, patella, and external femoral condyle; acromioclavicular luxation, and Monteggia's dislocation.

For the internal condyle, the associated injuries were: fracture of the leg, the intercondylar eminence, and the collateral external eminence: 1 case. With regard to location of the injury, we had 91 on the external condyle and 7 on the internal condyle.

For anatomical type, the relative frequency is shown in Table 2.

Table 2

(1) Tipo frattura	(5) Varietà	(8) N. casi
(2) Condiloidee esterne	lineari (6)	10
	con infossamento	18
	miste	63
(3) Condiloidee interne	lineari (7)	3
	con infossamento	4
(4) Totale		98

Key: 1 Type of fracture
2 External condylar
3 Internal condylar
4 Total
5 Variety
6 Linear
With sinkage
Mixed

7 Linear
With sinkage
8 No. of cases

The data are self-explanatory.

Statistically, mixed fractures are most frequent in the external condyle, followed by those with impaction, and those with impaction are more frequent in the internal condyle.

Results

We classified the clinical and radiological results as excellent, good, fair, and poor based on the criteria described in Part I. For the 91 fractures of the external condyle, the radiographic results are shown in the following table.

Table 3

(1) Risultati clinici	Risultati radiografici (7) Ottimi (2)	Buoni (3)	Discreti (4)	Cattivi (5)	Totale (6)
(2) Ottimi	9	8	7	—	24 (26,0%)
(3) Buoni	3	29	16	1	49 (53,8%)
(4) Discreti	—	4	5	8	17 (18,6%)
(5) Cattivi	—	—	—	1	1 (1,09%)
(6) Totale	12 (13,1%)	41 (45,1%)	28 (30,6%)	10 (10,9%)	91

Key: 1 Clinical results
2 Excellent
3 Good
4 Fair
5 Poor
6 Total
7 Radiographic results

For the results of fractures of the internal condyle, the values are shown as follows.

Table 4

(1) Risultati clinici	Risultati radiografici (7)				
	(2) Ottimi	(3) Buoni	(4) Discreti	Cattivi (5)	Totale (6)
(2) Ottimi	2	1	—	—	3 (42,8%)
(3) Buoni	—	1	2	1	4 (57,9%)
(4) Discreti	—	—	—	—	—
(5) Cattivi	—	—	—	—	—
(6) Totale	2 (28,5%)	2 (28,5%)	2 (28,5%)	1 (14,2%)	7

Key:
1 Clinical results
2 Excellent
3 Good
4 Fair
5 Poor
6 Total
7 Radiographic results

Finally, we related the clinical results to the anatomic type of the injury.

Table 5

(1) Tipo	(5) Varietà		Ottimi (10)	Buoni (11)	Discr. (12)	Cattivi (13)	Totale (4)
(2) condil. esterne	lineari (6)		2	6	2	—	10
	con (7) infossam.		5	12	1	—	18
	miste (8)		16	31	15	1	63
(3) condil. interne	lineari (9)		1	2	—	—	3
	con (7) infossam.		2	2	—	—	4
(4) Totale			79 (80,6%)		19 (19,4%)		98

Key:
1 Type
2 External condylar
3 Internal condylar
4 Total
5 Variety
6 Linear
7 With sinkage
8 Mixed
9 Linear
10 Excellent
11 Good
12 Fair
13 Poor

To summarize, satisfactory results, considering the excellent and good results together in both condyles, add up to 79, or 80%, while fair and poor results total 19, or 19%.

Conclusions

The conclusions that can be drawn from this material are obvious.

With our method, we obtained favorable results in 80% of the cases. Since these are joint fractures, we can consider this percentage to be satisfactory.

We believe that these favorable results are based on two factors: reduction without arthrotomy and bone transplant.

Although closed reduction gave us the good results we have presented, in some cases arthrotomy was needed for perfect reduction.

The radiographic results are not consistent with the clinical results. In fact, the clinical results are clearly better than the radiographic ones.

We also confirmed the observation that ligament injuries were infrequent. In fact, we observed only two injuries of the internal collateral in fractures of the external condyle and a single injury of the external collateral in fractures of the internal condyle. However, these injuries never required surgical treatment. We believe this confirms the hypothesis that, in the genesis of monocondylar fractures of the tibial plateau, the collateral ligament remains intact. It can suffer secondary injury after a fracture has already occurred if the traumatic force is not arrested or in cases of severe trauma when significant torsion is present.

Long-term joint instability observed in the cases we managed was not due to outcomes of the collateral injuries but to imperfect reduction of the fracture with persistence of displacement. We have not observed any long-term symptoms attributable to meniscal rupture or detachment, and for this reason we believe that exploratory arthrotomy is unnecessary. It can be justified only in cases when it is necessary to reduce the fracture.

If we consider the causes of the poor results, which are certainly the most significant cases, they can be reduced to three basic factors:

1) Varus or valgus deviation from the mechanical axis

2) The flexed position of the knee

3) Arthritic degeneration.

These three factors constitute a vicious circle that inevitably leads to pain and functional limitation.

DIAGNOSIS

REQUIRED

- Tenderness on physical exam at the spinous process of the involved level. AND
- MRI showing marrow edema at the fracture site OR, recent serial X-rays demonstrating acute (≤ 8 weeks) loss of height.
- If an MRI is contraindicated use a CT plus bone scan to determine osteopenia.

INDICATIONS

- Painful thoracic or lumbar vertebral body compression fracture due to osteopenia arising from primary or secondary osteoporosis or due to multiple myeloma.
- The residual vertebral body height as seen on X-rays is at least 8 mm at the posterior edge and the surgery is technically feasible.
- Documented history of symptomatic fracture for no more than 8 weeks.

CONTRAINDICATIONS

- Vertebral body fracture caused by high velocity injury.
- Vertebral body fracture with widened pedicles.
- End plate is depressed lower than the pedicle.
- Vertebral body burst fracture with retropulsion of fragments.
- Vertebral body fractures involving all 3 spinal columns.
- Vertebral body fracture due to solid tumors.
- Disabling back pain secondary to causes other than acute fracture.
- Patient is on anticoagulation therapy, which can not be discontinued.
- Bleeding disorder.
- Systemic or local infection.
- Documented history of symptomatic fracture(s) for greater than 8 weeks.
- Patient is under 40 years of age.
- Pregnancy

PRE-OPERATIVE PLANNING

- Notify the O.R. that you will need the KyphX kyphoplasty tools a C-arm and a compatible surgical table. You should also request that the operating suite be kept cold during the procedure.

The T8 to L5 vertebrae can usually be visualized in the OR with a C-arm. Levels above T7 may be harder to see without a high resolution C-arm. If there is no high-resolution C-arm available, you may wish to use a bi-plane fluoroscope in the X-ray suite. **Do not perform this procedure if you can not visualize the pedicles or other relevant spinal anatomy with your C-arm.**

- If using a spinal frame, ensure that it is radiolucent.

- Choose your approach based on your experience, patient status, and the width of the pedicles, which should be at least 5 mm wide on an MRI to accommodate the *Kyphon* Introducer Tools. The following approaches are guidelines:

The preferred approach is transpedicular unless the pedicles are too narrow

Approach	Level
Transpedicular	T10-L5
Extrapedicular	T5-T12
Posterolateral	L2-L4

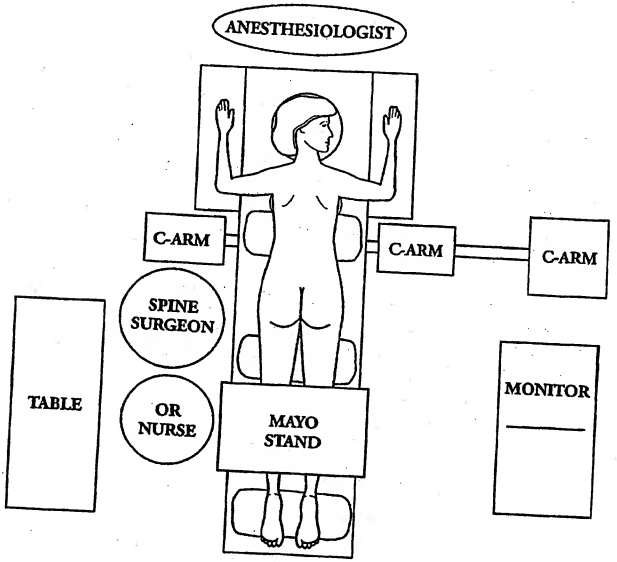
- For the posterolateral approach start from the side with the better quality bone, if that can be determined

- Select the appropriate KyphX Inflatable Bone Tamp size for each level on which you will be operating. The tamps are labeled according to their length and accessory tool size (e.g. 15/3 is a 15 mm balloon length used with a size 3 tool kit). Choose the Tamp size by measuring the mid-height length of the vertebral body in an oblique X-ray view. Select a Tamp whose deflated length is one half the vertebral body oblique mid-height length. Thoracic fractures typically require two size 15/3 Tamps. Lumbar fractures typically require two size 20/3 Tamps for the transpedicular approach and one size 25/3 Tamp for the posterolateral approach.

- Select the appropriate bone void filler, ensure that it is radiopaque and refrigerate a minimum of 12 hours if it is necessary to ensure appropriate consistency.

OR SETUP

One suggested operating room setup is shown below. A slave monitor should be positioned opposite the main monitor if the surgeon plans to switch sides during the procedure.



TRANSPEDICULAR APPROACH

This approach is appropriate for levels T-10 through L-5. On occasion the pedicles can be too small to accommodate the size 3 KyphX introducer tools and a posterolateral approach may be indicated. **It is imperative to use A-P, oblique and lateral imaging to guide this approach. Do not use this appro if the superior endplate is inferior to the pedicle.**

1. Use a pedicular *en face* view of the vertebrae to begin insertion of the needle (Figure 10). The pedicle image will be at its widest and brightest in this view. To achieve this view, position the C-arm ten to twenty degrees lateral to a true A/P view (Figure 11).

Figure 10

2. Using A-P and lateral images insert the needle into the upper 1/3 of the pedicle (Figure 10). Aim the needle inferiorly toward the middle of the vertebral body. Push or gently tap the needle creating a cortical window at the posterior cortex. Continue insertion 3-4 mm past the posterior wall of the vertebral body. Always use radiographic guidance to monitor tool placement (Figure 11).

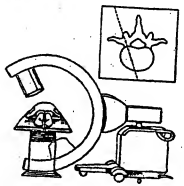


Figure 11

3. Remove the inner stylet from the needle and insert the guide pin. Advance the guide pin 2-3 mm past the end of the needle; you will feel the purchase (Figures 12a, 12ab)

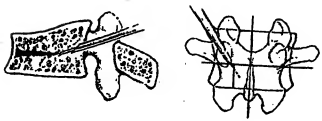


Figure 12a. Lateral and A-P view of entry points

Figure 12b. *En Face* view of guide pin entry point

4. Remove the needle, holding the guide pin in place.

5. Make a 1 cm incision across the skin surrounding the guide pin. Slide the blunt dissector over the guide pin and attach the Slip-Loc™ Handle (Figure 13a). Retract the surrounding tissue by advancing the blunt dissector to the surface of the vertebral body. Further increase the cortical window in the vertebral body by pushing the blunt dissector to just beyond the posterior cortex of the vertebral body. Verify position using radiographic images.

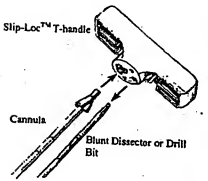


Figure 13a.

Figure 13b. A-P view of cannulas in position, the tools should enter the pedicles traveling in an inferior and medial direction.

6. Remove the Slip-Loc™ Handle from the blunt dissector and attach it to the cannula. Advance the cannula through the soft tissue to the end of the blunt dissector. Verify position of the cannula at the vertebral body wall using lateral radiographic images (Figure 13b.). Remove the Slip-Loc™ Handle.

7. Remove the guide pin and the blunt dissector, leaving the cannula in place.

8. Introduce the size 3 drill bit through the cannula.

CAUTION: Density of osteoporotic bone is variable. Always use continuos fluoro while drilling across the vertebral body.

9. Attach the Slip-Loc™ Handle to the drill bit. Using a gentle, clockwise rotating motion, advance the drill forward into the inferior portion of the vertebral body. When the drill is half way across on the lateral image, stop and take an A-P image to verify the drill position is not too medial. Return to the lateral image and proceed drilling under fluoro. Stop approximately 3-5 mm from the anterior cortex. (Figures 14a, 14b.)

10. **Verify the position of the drill bit tip relative to all cortices. Do this by rotating the C-arm 180° while using continuous fluoroscopy.**

11. Remove the drill bit from the cannula by rotating the Slip-Loc™ Handle counterclockwise.

12. Insert the Inflatable Bone Tamp and inflate to 50 psi (see next section for Inflatable Bone Tamp Instructions.) Repeat steps 1-12 for the opposite pedicle.

Figure 14a *Lateral view with drill in place.*

Figure 14b. *A-P view of drill bits in position.*

PLACEMENT AND INFLATION OF THE KYPHX™ INFLATABLE BONE TAMP- Transpedicular Approach

PRESSURE GAUGE MONITORING DURING INFLATION

Caution: Anterior cortical wall fractures can be difficult to detect in their early stages and must be diligently monitored during Tamp inflation.

1. Place the white insertion sleeve of the Inflatable Bone Tamp over the end of the cannula and advance the Tamp through the cannula to the end of the drill channel. Using A-P oblique and lateral imaging, locate the two marker bands on the Tamp. The marker bands should exit the cannula and should be equidistant from the anterior and posterior cortices. (Fig. 15) Remove the stylet from the Tamp.

2. Release the vacuum on the inflation syringe. Inflate the Bone Tamp in 0.5 cc increments by turning the handle of the Inflation Syringe clockwise one full turn (360°). **Do not exceed the maximum recommended inflation pressure of 220 psi.** At each 0.5 cc increment take an AP, oblique and lateral image to monitor the balloon position relative to the cortical walls. Check the pressure at each increment to ensure that it is decaying. Alternate inflation from side to side after each volume increment.

3. RECORD THE FINAL BONE TAMP VOLUME ON EACH SIDE. THIS IS IMPORTANT AS A MEASUREMENT OF THE CAVITY VOLUME CREATED TO AVOID OVERFILLING WITH BONE VOID FILLER.

Inflation ceases when any of the following occur:

- Height is restored to the vertebral body.
- The Bone Tamp touches any cortical wall or end plate.
- Cortical wall fracture.
- Pressure is at maximum 220 psi and there is no decay.

Maximum volume is reached as follows:

Size	Max. Vol.
25/3	8 cc
20/3	6 cc
15/3	4 cc

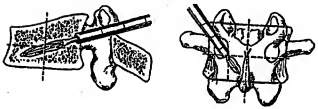
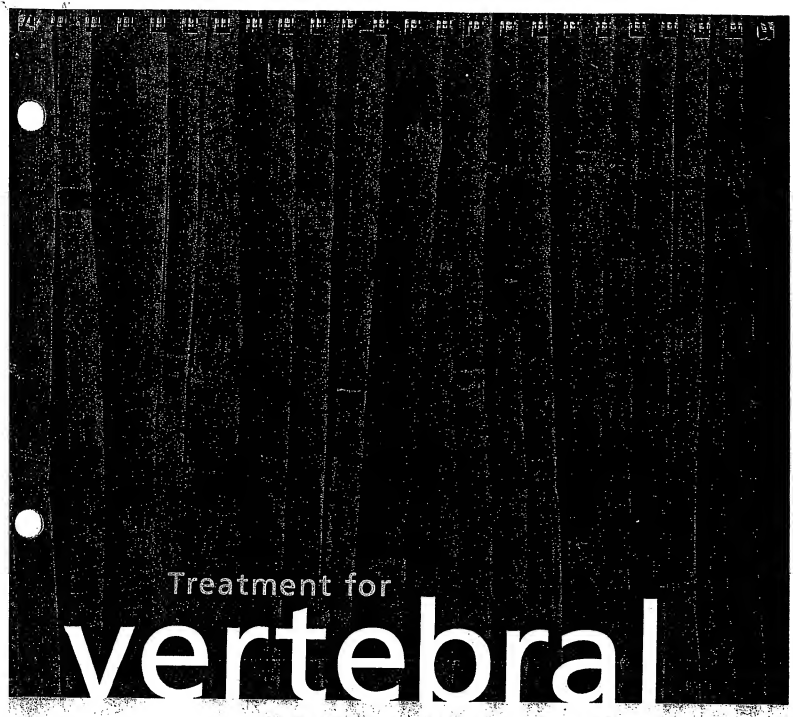
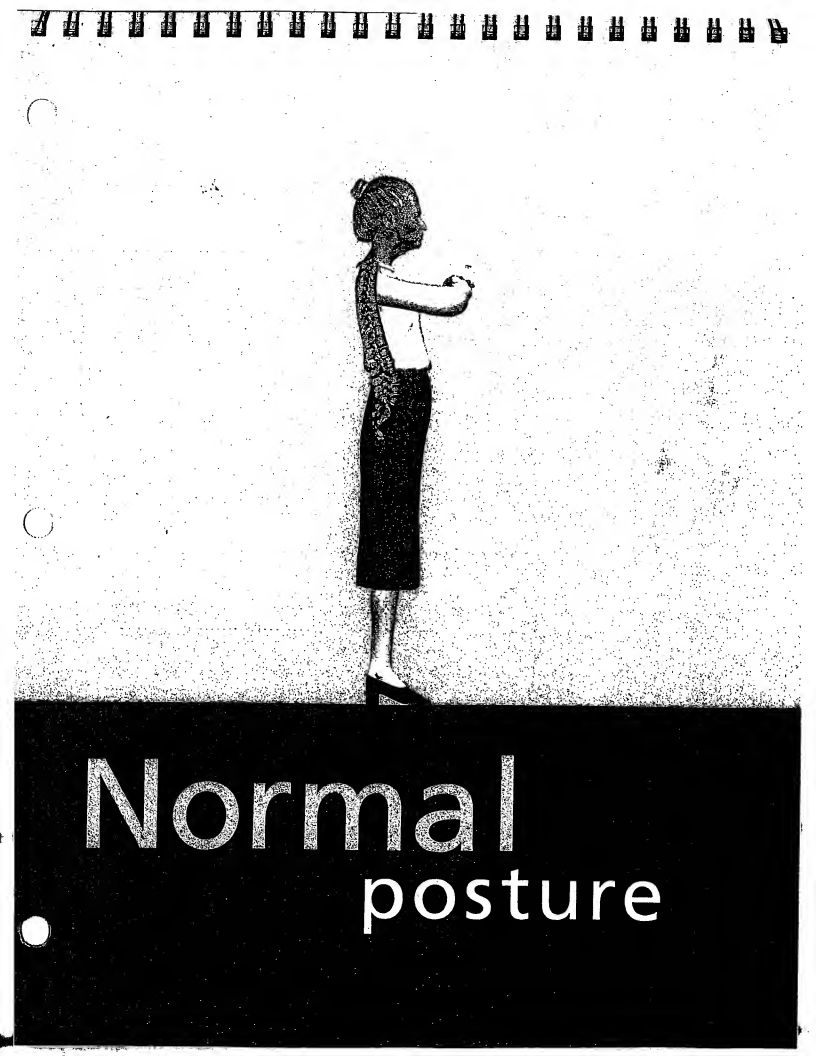


Figure 15 Introduction of the Inflatable Bone Tamp into the vertebral body using the transpedicular approach. Note the position of the radiopaque marker band in the lateral (left) and A-P(right) views.

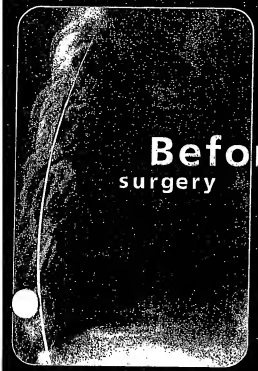


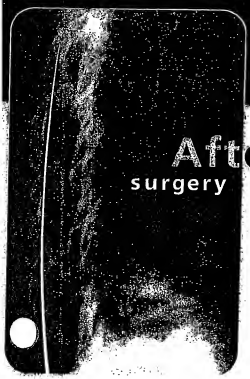
Treatment for

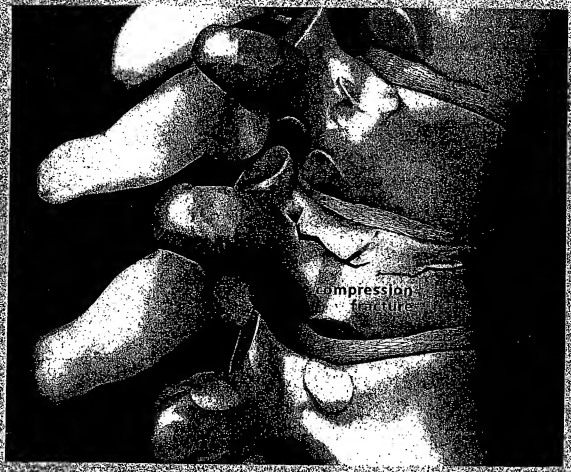
vertebral body compression fractures and back pain


Normal
posture

Deformity following multiple compression fractures

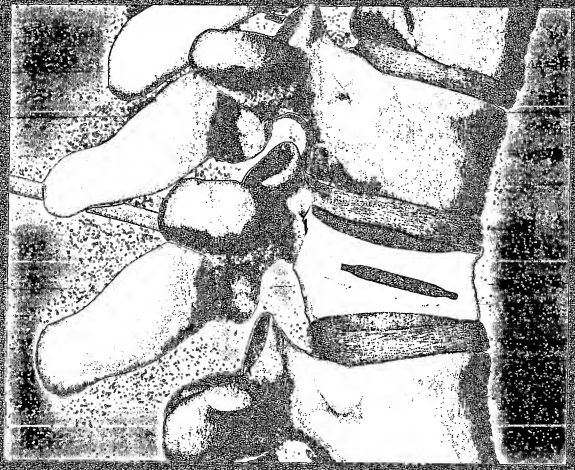






Fractured vertebral body

KYPHOPLASTY™



Minimally invasive

balloon

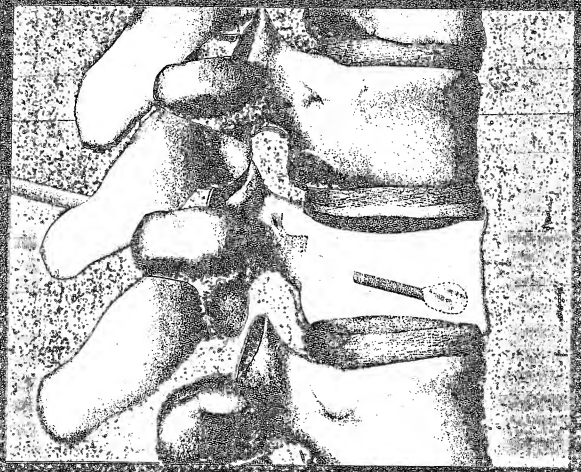
insertion

Balloon inflation to

and create

space

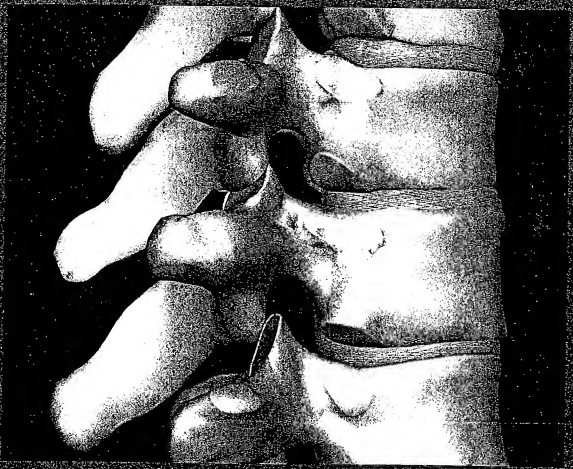
KYPHOPLASTY™



Filling the Space

Space

FOLLOWING KYPHOPLASTY™

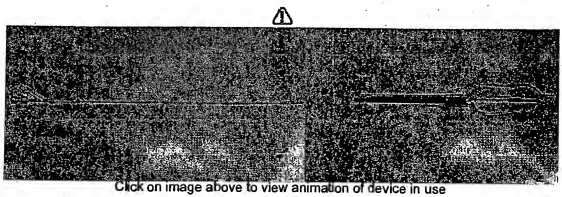


Fracture set

KyphX Products

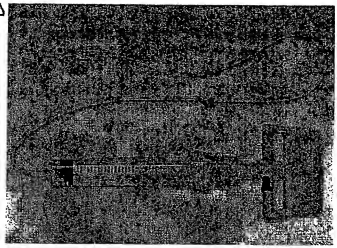
The following KyphX products are used for the minimally-invasive reduction of fractures involving crushed or collapsed bone.

KyphX Inflatable Bone Tamp (IBT)
The KyphX IBT is our proprietary device that is intended to be used as a conventional bone tamp for the reduction of fractures and/or the creation of a void in cancellous bone. The IBT is placed into the fractured bone through a cannula and then carefully inflated, achieving an "en masse" reduction of the crushed bone, and creating a cavity. Creating a cavity facilitates a low pressure fill with a thick, viscous material. After maximum inflation has been achieved, the IBT is deflated and withdrawn.

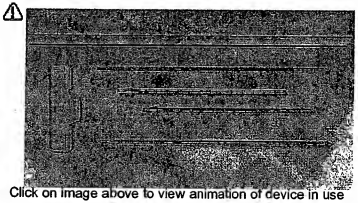


Click on image above to view animation of device in use

KyphX Inflation Syringe
The KyphX Inflation Syringe is used to inflate the KyphX IBT. A digital pressure gauge allows the physician to monitor inflation pressure, and numbering on the side of the inflation barrel facilitates measurement of inflation volume. The ergonomic handle and threaded plunger enable controlled inflation and deflation.

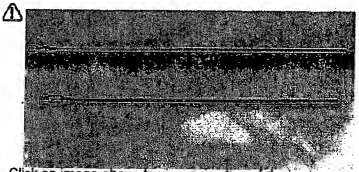


KyphX Bone Access System
The KyphX Bone Access System is a sterile set of small disposable surgical tools for reaching and creating a small (~4 mm) working channel inside the fractured bone. This set contains two long guide pins, a blunt dissector (an instrument used to separate tissue), a small Precision hand drill, a proprietary Slip-Loc t-handle which can be used with multiple tools, and two small cannulas (tubes) through which other tools are passed.

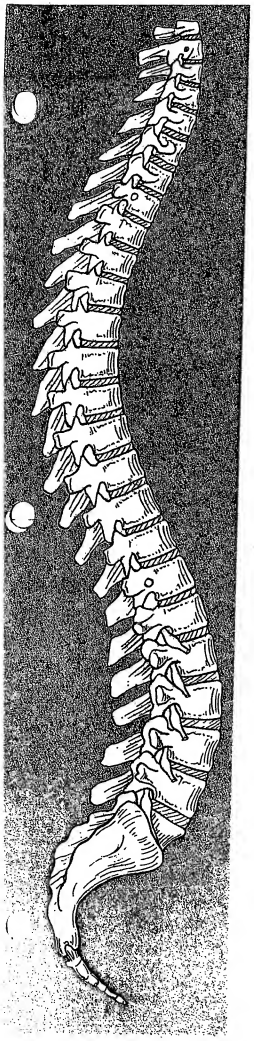


Click on image above to view animation of device in use

KyphX Bone Filler Device (BFD)
The KyphX Bone Filler Device is a sterile nozzle with an inner rod. Bone filler can be loaded into the nozzle and pushed into the cavity with the inner rod under low pressure and fine manual control.



Click on image above to view animation of device in use



Technique Manual

Controlled Delivery for Osteoplasty

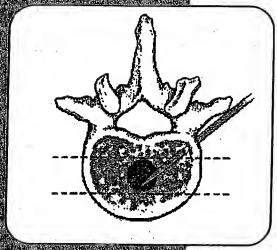
A Vertebroplasty Application

AOM

American OsteoMedix

Introduction

Vertebroplasty is a percutaneous technique for injecting biological substances into vertebral bodies weakened due to osteoporosis, tumor, or other pathological conditions. Vertebroplasty treatment, or spinal osteoplasty, serves to reinforce these weakened or collapsed vertebral bodies and thereby reduce pain and halt further compression and deformity. There are two percutaneous techniquees for spinal vertebroplasty: the transpedicular and the posterolateral. The transpedicular technique, though more popular at this time, is best done under CT Scan or biplane fluoroscopy. This technique can be very demanding and places the nerve root and spinal cord at greater risk of injury. This is even more significant in the thoracic spine where tolerances and pedicle sizes are smaller than in the lumbar spine.



Vertebroplasty

This technique manual has been developed to provide the surgeon with an alternate technique for gaining access to, and subsequent injection of biocompatible materials into, the vertebral body. The method presented here is similar to those utilized for discography or for percutaneous/arthroscopic disc excisions. There is a larger safe area on the posterolateral corner of the vertebral body compared to the disc space, making this an easier proceedure than discography.

In both the thoracic and lumbar regions, a posterolateral technique can be utilized; the angles for the technique; however, are quite different in each region of the spine. In the thoracic region the technique is similar to that done for thoracic discography, but with the placement of the needle above or below the rib into the thoracic vertebra. However, there is much more space, as the anterolateral aspects of the lumbar spine, particularly at the L3-L5 areas, are covered by the psoas. As the vertebroplasty is done at higher levels in the lumbar spine, a more medial technique is needed because of the smaller size of the psoas and concomitant risk to the blood vessels, specifically in the kidney and colon at Ll and L2.

In the thoracic region, the vertebroplasty angles are different from the lumbar spine. The technique angles are more vertical and the starting points are more medial to avoid possible pneumothorax. This is a complication associated with thoracic discograms approximately 5% to 25% of the time. In thoracic cases, the patient should be apprised of this additional potential risk and the possible need for a chest tube. Also, since vertebroplasty is performed on weakened vertebra, special care must be taken to avoid overpenetration of the bone by the guide wire or the subsequent cannulae through the opposing cortex and into the adjacent anatomy.

This Document is intended as a guide. The final choice of technique must depend upon patient anatomy, pathology, patient health status, and the surgeon's preference and judgement.

STEP I:

The positioning of the patient can be done either prone or in a lateral decubitus position. A Jackson-table or similar radiolucent operative table is necessary to allow for fluoroscopy. When utilizing the prone position, the abdominal cavity and viscera should be allowed to fall away from the spine because this offers a larger window for access to the spine. This also minimizes epidural venous engorgement and collateral blood flow near the nerve roots. Patient positioning will depend on table availability and surgeon preference. This manual is based on the prone technique but can be used as a guide for the lateral decubitius position.

STEP II:

Subsequent to positioning the patient and padding all dependent and vital areas, the patient is prepped and draped to allow for bilateral access. Under fluoroscopic guidance, markings are made in the lumbar and/or thoracic region corresponding to the trajectories of the cannula system. An initial vertical line is made along the spinous process at the sites to be treated. A transverse line is then drawn across the level of the pedicles. Finally, a second (targeting) lateral line can be drawn at the appropriate distance from and parallel to the central vertical line. The approximations for starting points are:

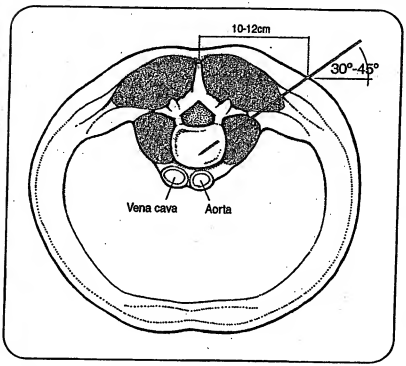
- **T10 & above:** 4-5 cm off mid-line – or approximately 2-3 cm lateral to the pedicles.
- **T11 to L1:** 5-7 cm off mid-line – because of the ribs a more central technique than L2 is needed.
- **L2 to L4:** 10-12 cm off mid-line – far lateral technique
  The technique will be much more lateral than typical for other spine procedures. L2 may only be 7-10 cm off mid-line, depending upon rib anatomy.
- **L5:** 10-12 cm off mid-line – For a patient with a low iliac crest the posterolateral technique can be utilized. The transpedicular technique is more appropriate for a high iliac crest, significant compression of L5, or large osteophytes at the L4-5 disc space.

These starting points will have to be modified and adjusted to a patient's body habitus as well as possible deformities (kyphosis, scoliosis). Surgeon judgement should be used to adjust any of the starting points or placements specified above.

Lumbar Vertebroplasty:

STEP III: At L2-L5 the initial placement of the guide wire is done approximately one handbreadth, or 10-12 cm, away from the spinous process. The angle of trajectory is approximately 45 – 60 degrees from the spinous process axis. Often, because of the lowest ribs, the starting point for L2 has to be more central, and the technique angle more vertical. The initial guide wire and subsequent cannulae should be placed on the posterolateral aspect of the vertebral body at the level of the pedicle.

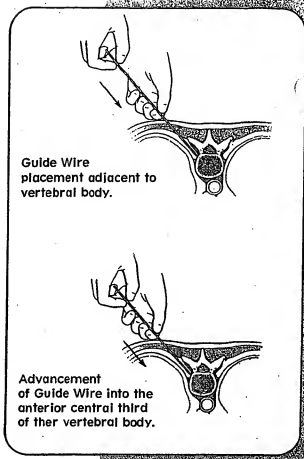
Caution: **It is essential to avoid the medial valley in each vertebral body in order to avoid the segmental vessels.**



STEP IV:

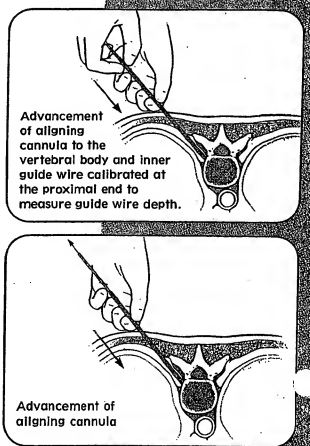
The guide wire is inserted through a small percutaneous stab incision placed at the above described starting points, under active A/P and lateral visualization with fluoroscopy, into the posterolateral corner of the vertebral body. The guide wire can be handled with the holding forceps or guide wire cap and should be tamped into the vertebral body for a distance of at least 1 to 1.5 cm to provide adequate purchase in the vertebral body. The point of the wire should be directed toward the central portion of the vertebral body and almost to midline as monitored on AP and lateral fluoroscopy. During initial placement of the guide wire, intraoperative EMG monitoring should help prevent any potential injury to the nerve roots.

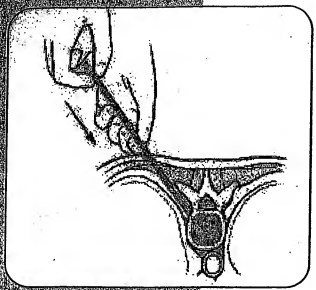
Caution: Do not create a starting hole in the vertebral body unless the guide wire is in the safe zone because any substance can extrude through this vent hole and cause nerve root compression. In the event that the guide wire is placed in a position which is not ideal, the surgeon may leave the guide wire in place and continue the surgery with a new guide wire. This technique is designed to maintain a seal in the bone during placement of the substance and the original guide wire should then be removed when the second outer cannula and plunger are removed.



STEP V:

Subsequent to placement of the guide wire, the aligning cannula is placed over the wire with a twisting motion as it goes through the fascial layers. Care should be taken to visualize this with fluoroscopy as often times the bone is so weak that the guide wire is liable to be pushed by the very small degree of friction between the aligning cannula and the guide wire. When the aligning cannula is in contact with the posterolateral surface of the vertebral body, the guide wire calibration can be measured against the cannula to determine the depth of the guide wire into the vertebral body. The cannula should then be tamped into the bone utilizing the gripping impactor or modular tamp. The aligning cannula should be placed into the bone such that the tapered portion of the cannula is fully inside the bone and flush with the guide wire at the desired depth. To ensure central placement of the substance, both devices should be near mid-line as noted on fluoroscopy in the AP and lateral views.





Advancement of outer cannula
Note: Handle provides leverage to facilitate control of outer cannula

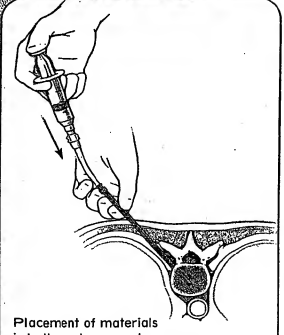
STEP VI:

The outer cannula should be attached via the luer lock to the modular tamp and is then placed over the aligning cannula to the bone surface utilizing a similar technique as that utilized for the inner cannula. A twisting motion moves the device through the fascial layers. The outer cannula is tamped with a mallet, again under fluoroscopy visualization, into the vertebral body. The outer cannula should be advanced to an even point with the other devices toward the central portion of the vertebral body as noted on the lateral and the A/P views. Following placement of the outer cannula, the three devices should be left in the patient during preparation of the implant. This will maintain a fill in the outer cannula and prevent blood and fluids from tracking up the cannula.

STEP VII:

This procedure is suitable for use with any substance deemed acceptable by the operating surgeon for implantation by manual vertebroplasty. The inner diameter of the outer cannula is 6 mm and the only limiting factors for any substance utilized by the surgeon are the volume, size and viscosity of such material. As a guideline only, the volume of substance should ordinarily not be greater than 7 cc for each lumbar level, but may vary depending upon the volume of the vertebral body. Thoracic vertebral bodies tend to require less substance due to the anatomical size, as do compressed bodies. Intact bodies with significant osteoporosis will usually accept 5 cc to 7 cc.

Caution: The substance to be implanted must be prepared according to the manufacturer's instructions and placed into the syringe.

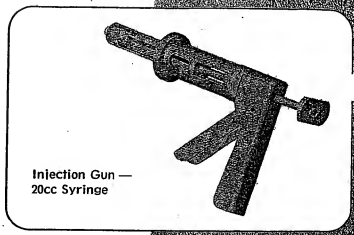


Placement of materials into the outer cannula
Note: Injection Gun provided to facilitate more precise metering of substance for the initial placement of such material into the outer cannula

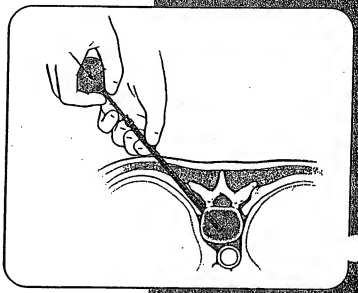
STEP VIII:

Remove the inner cannula and guide wire prior to injection of the substance. Attach the connecting hose to the outer cannula to help prevent excessive pressure on the cannula during administration. Excessive pressure can result in advancing the outer cannula through the vertebral body. An injection gun may be used if mechanical advantage is necessary to advance the substance into the outer cannula. The substance is then injected through the connecting hose and into the cannula. The outer cannula holds approximately 3.5 cc of the material, while the connecting hose holds an additional 1 cc. The mechanical advantage of the injection gun should be noted when advancing the material. The plunger is designed to place any substance into the bone under lower pressures and the injection gun should only be used to load the outer cannula. The syringe and hose are then removed from the luer lock leaving 3.5cc of the material in the cannula. The plunger is utilized and, under live lateral visualization, should be advanced to push the material into the vertebral body in a controlled manner. The outer cannula is designed to allow the visualization of a radio opaque material, while monitored under fluorosopy, while such material is in the cannula.

The plunger provides tactile feedback during the advancement of the substance into the body. The plunger system also provides a mechanical advantage which allows for the placement of substance which may be more viscous at the time of injection. The plunger is designed to decrease pressure by allowing air to escape through the small tolerance between the plunger and the outer cannula. The inner volume of the cannula is approximately 3.5 cc. The diffusion of material is best visualized on the lateral fluoroscopy.

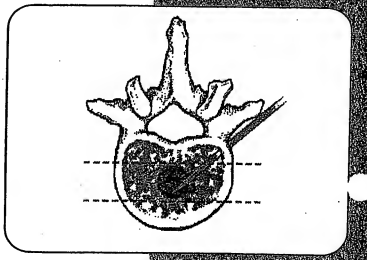

Injection Gun —
20cc Syringe

Caution: Care needs to be taken at the time of injection to ensure there is no filling beyond the posterior margin of the vertebral body. This is to ensure that the material remains within the limits of the vertebral body and avoids the foramen of the spine. The amount of substance injected will need to be modified to be sure that this does not occur. To decrease the possibility of pulmonary embolus, the substance utilized should not be too liquid or at low viscosity; the plunger system (6mm inner diameter) has the advantage of placing a more viscous material into the vertebral body. Consult the package insert of any implant for labeling guidelines before use.



It is always possible to move to the opposite side of the patient for additional fill of material if necessary. Bilateral injections are not always deemed as necessary, but for a complete fill of the vertebral body, it may be the preferred technique.

Caution: A unilateral injection of too much material increases the risk and potential for compromise of neural structures. Care must be taken particularly when injecting collapsed vertebral bodies; these vertebra need much less substance and the implant may tend to diffuse across the breadth of the vertebral body. Injection into metastatic or malignant lesions of the vertebral bodies is riskier because if a posterior cortical break exists there is an increased chance for extrusion. If there is no cortical breakthrough then injection is often not be more difficult than in the osteoporotic situation.



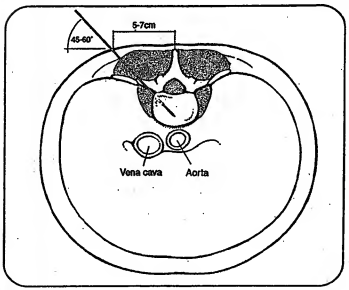
Note: Pre-operative films (CT and MRI) will help determine potential defects and are beneficial when performing any percutaneous application of material into the bone.

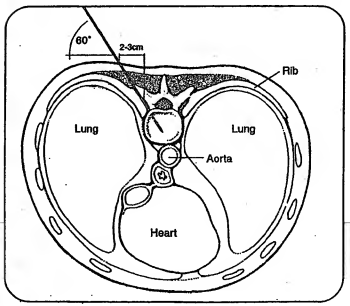
STEP IX:

Once the substance has been injected, and the plunger is down to the desired depth, the materia is allowed to complete any chemical or biological changes described in the package insert provided with the material. In cases which the substance used "cures into a hardened state," the plunger and cannula should uniformly be rotated occasionally to prevent the bonding of the cannula to the vertebral body. Once this substance has cured, the cannula system can be removed. This waiting process is intend ed to help ensure that a trail of less viscous material is not left in the soft tissue at the time of removal.

Caution: In situations which the substance chosen does not cure, care must be taken to avoid leaving material in the soft tissue as the cannulae's are extracted.

L1 and Non-Lumbar Vertebroplasty:

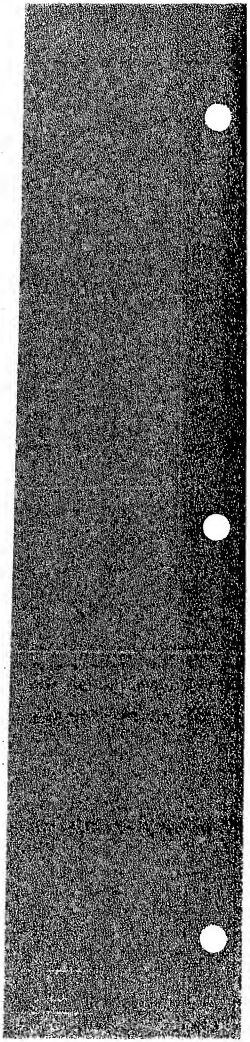


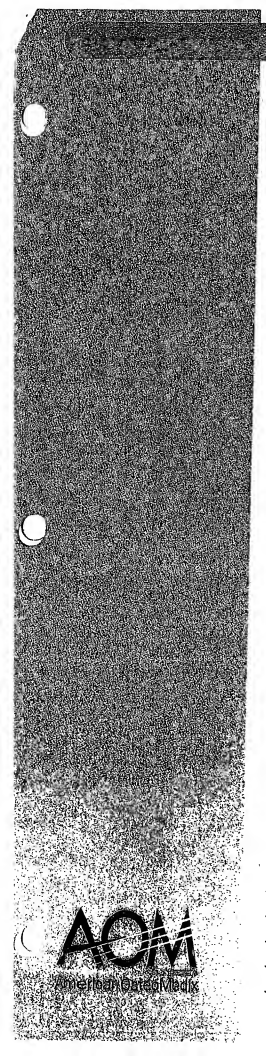


STEP X:

Non-lumbar placement can be more challenging than lumbar vertebroplasty. The anatomy is quite different from that in the lumbar area. In the upper thoracic region the technique is done with the guide wire just lateral to the articulation of the rib head and the transverse process of the thoracic vertebra. The angle is much different from that used in the lumbar spine; the technique angle is approximately 60 - 70 degrees from the patient's back, (or 25 to 40 degrees measured off the vertical axis of the spinous process). A vertical line is drawn down over the lateral margins of the thoracic pedicles, and the starting point is 2 cm to 3 cm lateral to this in line with the vertebral body to be injected.

Caution: As noted for the lumbar vertebral body, the segmental artery must be avoided. Targeting of the guide wire should be just lateral to the pedicle and at the posterior aspect of the body. The sequence is then the same as those for a lumbar technique. Note the volume required for the thoracic vertebral bodies will be smaller; approximately 3 cc to 4 cc's. Finally, the starting points as measured by using the above technique for L1 and T12 should be 5 cm to 7 cm off mid-line. The exact placement will depend upon the rib anatomy, and the angle of trajectory will be somewhat between the thoracic and lumbar vertebrae technique and approximately 30 to 45 degrees off the vertical axis of the spinous process. Finally, the transpedicular technique for sequencing and using of the instruments and injection of the material remains the same as that noted throughout this manual.

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64A Sycolin Rd, SE
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www.osteomedix.com

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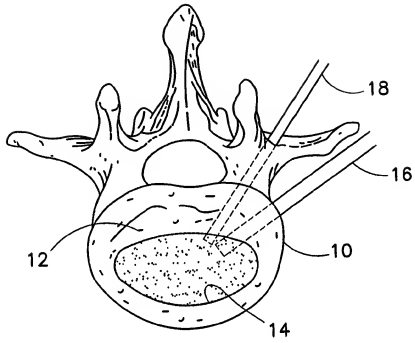


FIG. 1

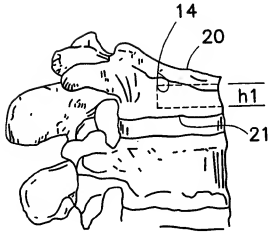


FIG. 2

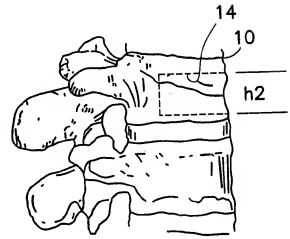


FIG. 3

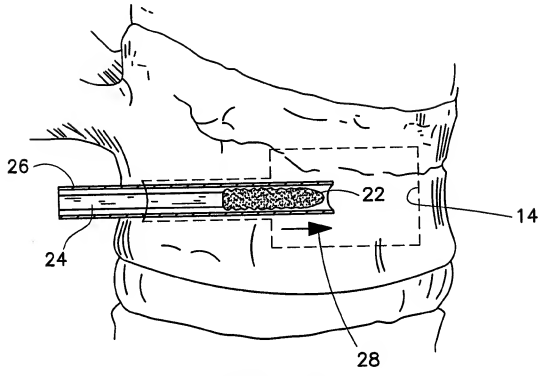


FIG. 4

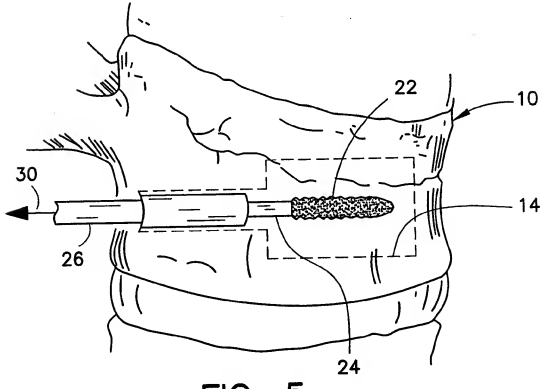


FIG. 5

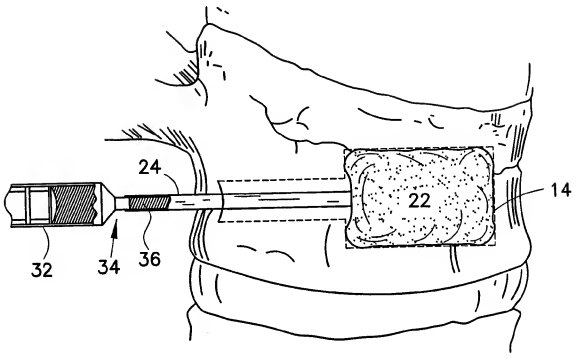


FIG.6

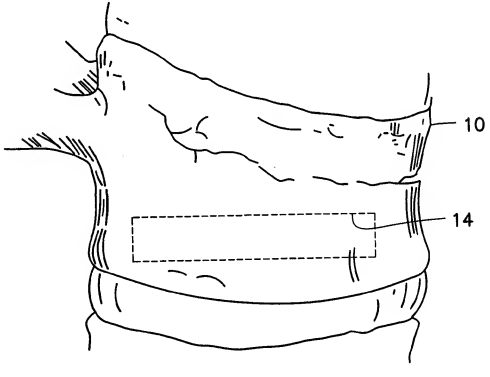


FIG. 7

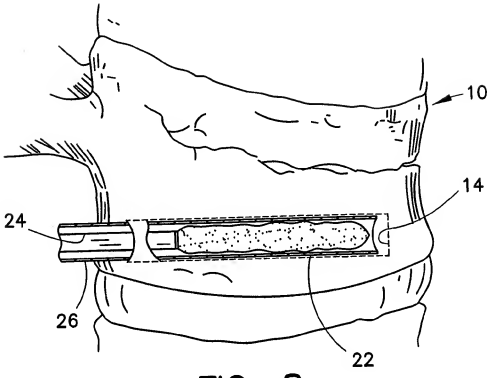


FIG. 8

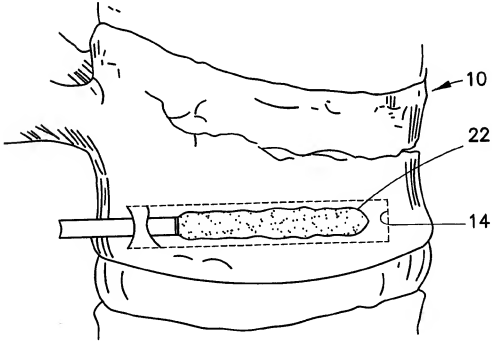


FIG. 9

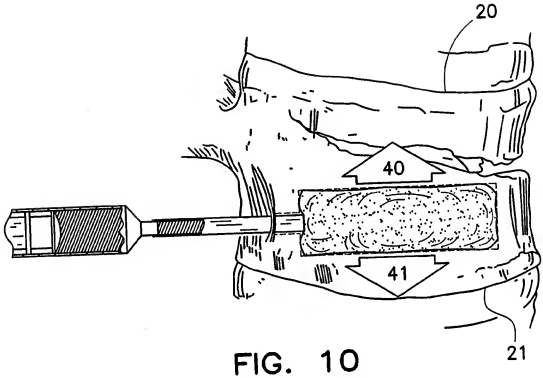


FIG. 10

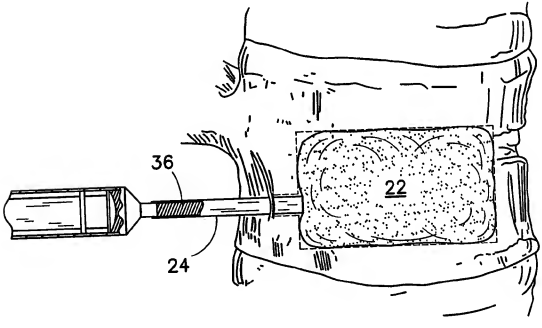


FIG. 11

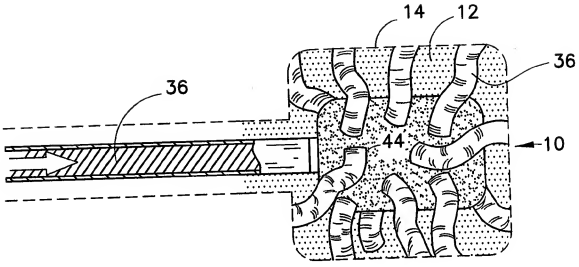


FIG. 12

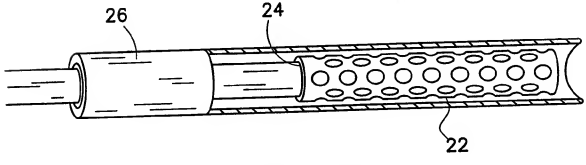


FIG. 13

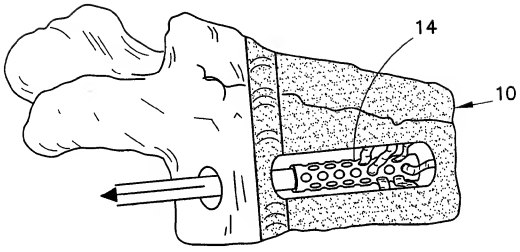


FIG. 14

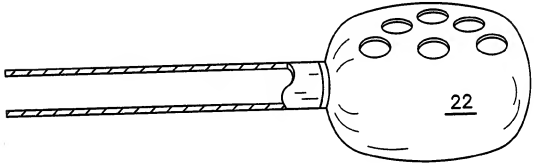


FIG. 15

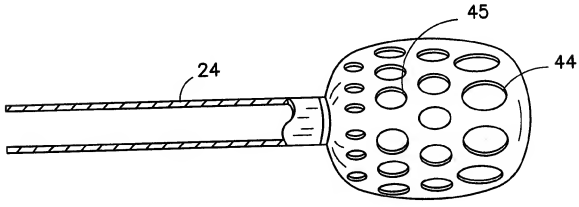


FIG. 16

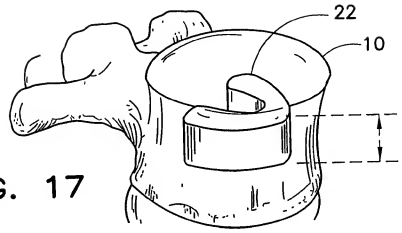


FIG. 17

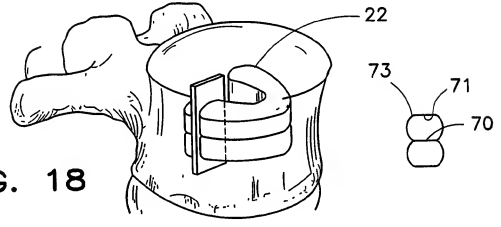


FIG. 18

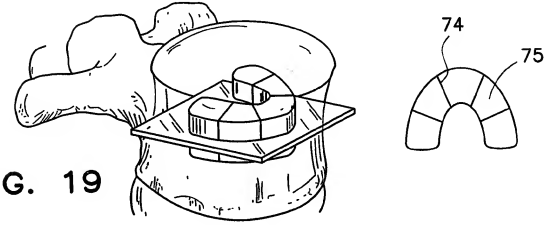


FIG. 19

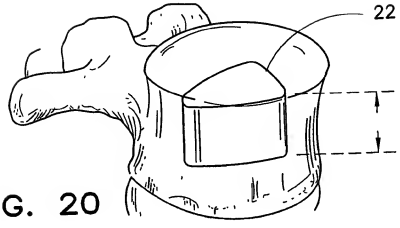
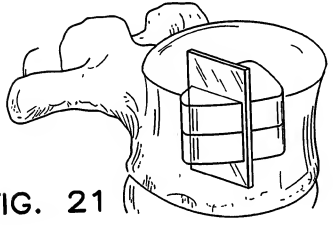


FIG. 20



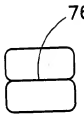
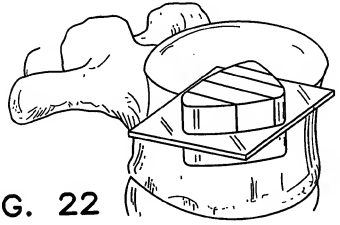


FIG. 21



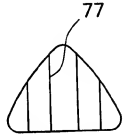


FIG. 22

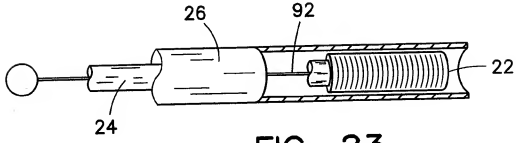


FIG. 23

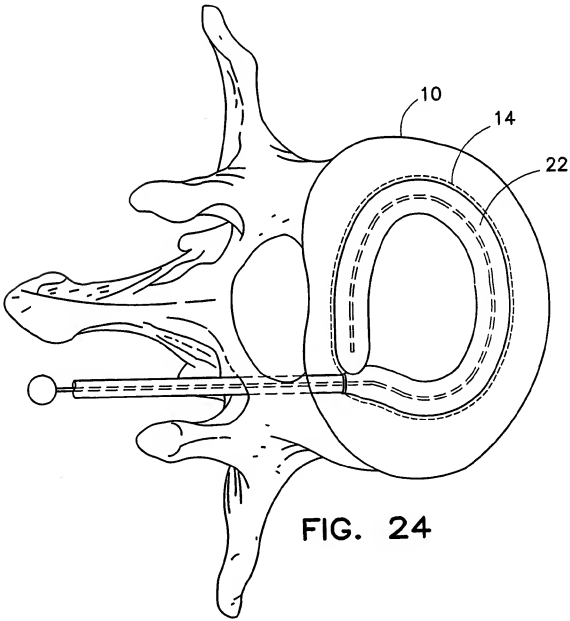


FIG. 24

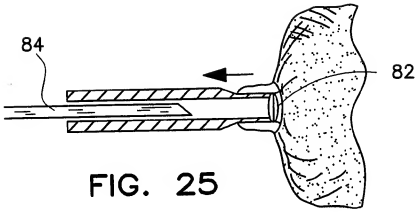


FIG. 25

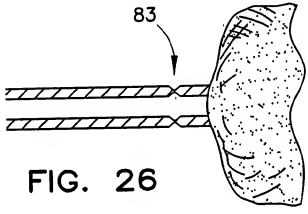


FIG. 26

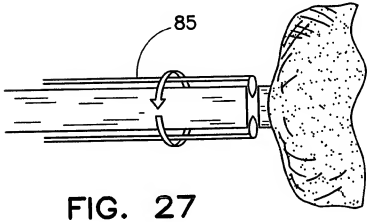


FIG. 27

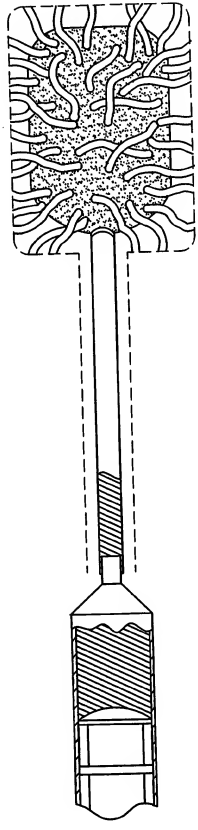


FIG. 28

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
PO Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/804,955	03/19/2004	Stephen Hochschuler	1842-0038

CONFIRMATION NO. 8076

Michael D. Beck
Suite 3000
111 Monument Circle
Indianapolis, IN 46204-5115

FORMALITIES LETTER

OC000000012851203

Date Mailed: 06/04/2004

NOTICE TO FILE CORRECTED APPLICATION PAPERS

Filing Date Granted

An application number and filing date have been accorded to this application. The application is informal since it does not comply with the regulations for the reason(s) indicated below. Applicant is given TWO MONTHS from the date of this Notice within which to correct the informalities indicated below. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121 are required. The drawings submitted are not acceptable because:
  - The drawings have a line quality that is too light to be reproduced (weight of all lines and letters must be heavy enough to permit adequate reproduction) or text that is illegible (reference characters, sheet numbers, and view numbers must be plain and legible) see 37 CFR 1.84(l) and (p)(1)); See Figure(s) 8, 16, 14, 18, 23, 24, 25, 27.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

A copy of this notice MUST be returned with the reply.

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Initial Patent Examination Division (703) 308-1202

PART 3 - OFFICE COPY

UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.53(b))

Attorney Docket No.	1842-0038
First Inventor	Hochshuler et al.
Title	Method and Apparatus for Treating a Vertebral Body
Express Mail Label No.	EV389959275US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

1. ☑ Fee Transmittal Form (e.g., PTO/SB/17)
(Submit an original and a duplicate for fee processing)
2. ☑ Applicant claims small entity status.
See 37 CFR 1.27.
3. ☑ Specification [*Total Pages* 17]
(preferred arrangement set forth below)
- Descriptive title of the invention
- Cross Reference to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to sequence listing, a table, or a computer program listing appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

4. ☑ Drawing(s) (*35 U.S.C. 113*) [*Total Sheets* 11]
5. Oath or Declaration [*Total Sheets* 4]
a. ☐ Newly executed (original or copy)
b. ☐ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional with Box 18 completed)
i. ☐ DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) name in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
6. ☑ Application Data Sheet. See 37 CFR 1.76

7. ☐ CD-ROM or CD-R in duplicate, large table or Computer Program *(Appendix)*
8. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
a. ☐ Computer Readable Form (CRF)
b. Specification Sequence Listing on:
i. ☐ CD-ROM or CD-R (2 copies); or
ii. ☐ Paper
c. ☐ Statements verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

9. ☐ Assignment Papers (cover sheet & document(s))
10. ☐ 37 CFR 3.73(b) Statement ☐ Power of Attorney
(when there is an assignee)
11. ☐ English Translation Document *(if applicable)*
12. ☐ Information Disclosure Statement (IDS)/PTO-1449 ☐ Copies of IDS Citations
13. ☑ Preliminary Amendment
14. ☐ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
15. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
16. ☐ Nonpublication Request under 35 U.S.C. 122 (b)(2)(B)(i). Applicant must attach form PTO/SB/35 or its equivalent.
17. ☑ Other: Return Postcard.....

18. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:*

☐ Continuation ☑ Divisional ☐ Continuation-in-part (CIP) of prior application No. 09/794,873

Prior application information: *Examiner* M. Priddy *Art Unit:* 3732

For CONTINUATION OR DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

☑ Customer Number: 28078 *OR* ☐ Correspondence address below

Name	Maginot, Moore & Beck				
Address	Bank One Center/Tower 111 Monument Circle, Suite 3000				
City	Indianapolis	*State*	IN	*Zip Code*	46204-5515
Country	US	*Telephone*	317-638-2922	*Fax*	317-638-2139

Name (Print/Type)	Michael D. Beck	*Registration No. (Attorney/Agent)*	32,722		
Signature	Michael D. Beck			*Date*	March 19, 2004

PTO/SB/17 (10-03)
Approved for use through 07/31/2006. OMB 0651-0032
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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☑ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 457.00

Complete if Known	
Application Number	To be assigned
Filing Date	March 29, 2004
First Named Inventor	Hochschuler et al.
Examiner Name	To be assigned
Art Unit	To be assigned
Attorney Docket No.	1842-0038

METHOD OF PAYMENT *(check all that apply)*

☑ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account:

Deposit Account Number: 13-0014

Deposit Account Name:

The Director is authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☑ Credit any overpayments

☐ Charge any additional fee(s) or any underpayment of fee(s)

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	385.00
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($) 385.00

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims		Fee from below	Fee Paid
Total Claims	28	-20** = 8	X	9	= 72
Independent Claims	3	- 3** = 0	X	43	= 0
Multiple Dependent					=

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 72.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) _____

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($) 0.00

SUBMITTED BY				(Complete *(if applicable)*)	
Name (Print/Type)	Michael D. Beck	*Registration No. (Attorney/Agent)*	32,722	*Telephone*	317-638-2922
Signature				*Date*	March 19, 2004

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This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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DIVISIONAL PATENT APPLICATION

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Date of Deposit March 19, 2004

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Michael D. Beck
Name of person mailing Document or Fee

Signature of person mailing Document or Fee

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Maplewood, MN 55119

Tyler Lipschultz
6112 Avalon Drive East
New Canaan, CT 06840

METHOD AND APPARATUS FOR TREATING A VERTEBRAL BODY

Michael D. Beck
Registration No. 32,722
Attorney Docket No. 1842-0038

Correspondence Address:
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Bank One Center/Tower
111 Monument Circle, Suite 3000
Indianapolis, Indiana 46204-5115
Telephone: (317)638-2922
Facsimile: (317)638-2139

Method and Apparatus for Treating a Vertebral Body

Cross-reference to related cases

The present case claims the benefit of the following Provisional Applications: "Cavity Sealing Barrier", serial number 60/185,323, filed 2/28/2000 ; "Implant for Hard Bones", serial number 60/220,303, filed 7/24/2000 ; "Vertebral Body Sealing Device and Method", serial number 60/239,216, filed 10/10/2000; "Hydraulic Distraction with Permeable Membrane", serial number 60/239,217 , filed 10/10/2000 and incorporates each of these by reference in their entirety.

Field of the Invention

The present invention relates generally to the treatment of bones and more particularly to the treatment of the vertebral bodies found in the human spine.

Background of the Invention

The human spine consists of a complex set of interrelated anatomic elements including a set of bones called vertebral bodies. Intervertebral discs separate most vertebral bodies. These discs includes a "spongy" nucleus pulpous surrounded by an annulus fibrosis "membrane". The annulus fibrosis connects the opposed endplates of adjacent vertebral bodies. All of these structures together with muscles act to provide motion, stability and protection for the spine. When healthy, these structures effectively protect the spinal cord and allow for normal motion.

However there are many disease states and aging processes that impact the patient. Osteoporosis and metastatic disease reduce the structural integrity of the vertebral bodies, predisposing them to fracture. Vertebral fractures can lead to loss of vertebral height which can exacerbate existing neurological condition or it can predispose the spine to other symptoms. Back pain often results from these conditions. Vertebroplasty is an effort to stabilize these fractures and to alleviate this source of pain.

Generally, fractures and loss of height if not treated results in a cascade of injury which is undesirable. For this reason various efforts have been directed at stabilizing and restoring the natural vertebral bodies of the back. Efforts have also been directed to replacing the vertebral bodies.

condition or it can predispose the spine to other symptoms. Back pain often results from these conditions. Vertebroplasty is an effort to stabilize these fractures and to alleviate this source of pain.

Generally, fractures and loss of height if not treated results in a cascade of injury which is undesirable. For this reason various efforts have been directed at stabilizing and restoring the natural vertebral bodies of the back. Efforts have also been directed to replacing the vertebral bodies.

US Patent 5,108,404 to Scholten et al among others teaches a technique for height restoration that uses a bone cement product introduced into a cavity after a cavity has been made with an inflatable device. One problem with this system is the extravasation of bone cement to sensitive areas. Another problem is the difficulty of obtaining consistent control of height restoration with the Scholten system.

Summary

In contrast to the prior art, the present invention involves both a container device that is permanently implanted and a method of using the container to stabilize the vertebral body or to restore height to the vertebral body.

In one embodiment the container is porous to the bone filler material. In another embodiment the container is impermeable to the bone filler material. In each embodiment the container controls and regulates the delivery of bone filler material into the vertebral body.

In one embodiment the container is flexible and conformal to the cavity. In another embodiment the container has a fixed shape which conforms to the cavity shape when deployed.

In one embodiment of the method, the bone filler is injected until the cavity is completely filled stabilizing the vertebral body. In another embodiment of the method the bone filler is injected and displaces the endplates of the vertebral body "restoring height" through a hydraulic jacking effect and stabilizing their vertebral body.

There are numerous bone filler materials which can be used to fill the container including bone cement and other materials. However it is a general property of the bone fillers that they must be injectable in a fluid state and that they harden.

Brief Description of the Drawings

Throughout the several views of the drawings there are shown illustrative embodiments of the inventions in which like reference numerals indicate equivalent or identical structure, wherein:

Fig. 1 is a sectional view of a vertebral body;

Fig. 2 is a view of a vertebral body in elevation;

Fig. 3 is a view of a vertebral body in elevation;

Fig. 4 is a view of a vertebral body with items shown in phantom view;

Fig. 5 is a view of a vertebral body with items shown in phantom view

Fig. 6 is a view of a vertebral body with items shown in phantom view

Fig. 7 is a view of a vertebral body with items shown in phantom view

Fig. 8 is a view of a vertebral body with items shown in phantom view

Fig. 9 is a view of a vertebral body with items shown in phantom view

Fig. 10 is a view of a vertebral body with items shown in phantom view;

Fig. 11 is a view of a vertebral body with items shown in phantom view;

Fig. 12 is a view of an embodiment of a porous container in use;

Fig. 13 is a view of an embodiment of a porous container;

Fig 14 is a view of a porous container in a cutaway vertebral body;

Fig. 15 is a view of a container in isolation;

Fig. 16 is a view of a container in isolation;

Fig. 17 is a perspective view of a container in a vertebral body;

Fig. 18 is a perspective view of a container in a vertebral body;

Fig. 19 is a perspective view of a container in a vertebral body;

Fig. 20 is a perspective view of a container in a vertebral body;

Fig. 21 is a perspective view of a container in a vertebral body

Fig. 22 is a perspective view of a container in a vertebral body

Fig. 23 is a view of a tubular container;

Fig. 24 is a view of a tubular container in use;

Fig. 25 is a view of a fill tube construction;

Fig. 26 is a view of a fill tube construction;

Fig. 27 is a view of a fill tube construction; and,

Fig. 28 is a view of an alternate porous container embodiment.

Detailed Description

The various container devices and the methods for using the container devices are disclosed in the context of the treatment of vertebral bodies. It should be recognized that the inventions may be used in other bones which present the same or similar pathologies, including but not limited to tibial plateaus, distal radius fractures, calcaneous fractures.

Fig. 1, Fig. 2 and Fig. 3 taken together are intended to show a cavity creation process that precedes treatment with the devices and methods of the invention. In general cavity creation techniques are well known and they may include the creation of a cavity with a balloon device as is known in the art.

Fig. 1 shows a vertebral body 10 in partial cross section. The exterior portion of the vertebra is dense cortical bone and the interior is porous cancellous bone which is labeled 12 in the figure. The cavity 14 is depicted by the dashed outline in the drawing and it is formed in the porous bone. The shape of the cavity depends on the technique used to form it. This cavity is made in a conventional way. For example a tool may be introduced through extra-pedicular access tube 16 or transpedicular access tube 18 and operated in the vertebral body. As seen in the drawing the extrapedicular access tube 16 may have a larger diameter and will be preferred by some surgeons. In general, the access approach for cavity creation will also be used for the introduction of the devices of the invention. These approaches will be used for the methods of the invention.

Fig. 2 shows a collapsed vertebral body 10 in elevation with a compression fracture and associated loss of height. The superior endplate 20 has moved due to a fracture and normal loading. The nominal height of the cavity formed in this vertebral body is labeled "h1" in the figure. As the end plate moves the angle formed between the superior endplate 20 and the inferior endplate 21 becomes acute which is undesirable. In the extreme case both sides of the endplates fall to form a severely compressed rectangular shaped vertebral body.

Fig. 3 shows a fractured vertebral body that requires intervention. In this vertebral body the height of the cavity 14 is indicated by the nominal height of the vertebral body labeled as "h2" in the figure.

Taken together the Figures 1, 2 and 3 represent the formation of a cavity 14 prior to treatment with device of the present invention.

Taken together Fig. 4 Fig. 5 and Fig. 6 represent steps in a method to stabilize a fractured vertebral body.

Fig. 4 shows a step in the method. In this drawing the container 22 is coupled to a fill tube 24 shown in phantom view. In this embodiment the container 22 is located at the distal end of a fill tube 24. The container 22 and fill tube 24 are carried together with the delivery tube 26. The motion arrow 28 indicates that the delivery tube 26 and fill tube 24 are being moved together into the surgically prepared cavity 14. The delivery tube 26 may be the same device that is used to deliver the cavity tools as discussed with reference to Fig. 1. Or the tube 26 may be a separate device inserted through an alternate access aperture.

Fig. 5 shows the deployment process step where the delivery tube 26 is retracted as indicated by motion arrow 30 while the fill tube 24 and the attached container 22 remain stationary in the vertebral body 10 cavity 14.

Fig. 6 shows the expansion of the container 22 within the cavity 14. The bone filler material 36 seen in phantom view has been loaded into the manually operated syringe 32 and the physician is injecting the material

through the fill tube 24 into the container 22. The container 22 has unfurled and conformed to the shape of the cavity 14. The unconstrained shape of this container is generally cylindrical with spherical ends. This figure shows the deployment of the container in to a cavity which is substantially the same volume as the cavity 14. In this illustrative example the volume of the container is larger than the volume of the cavity and there is no stretching force applied to the impermeable container membrane.

The coupling 34 between the fill tube and the syringe 32 may be a conventional luer lock or other attachment device. Although a syringe is an effective filler delivery tool it is expected that physicians will use an alternative delivery system such as a an extruder rod inserted directly into the fill tube to displace bone filler into the container.

Fig. 7 depicts the preliminary preparation of a cavity 14 in a collapsed vertebral body 10.

Fig. 8 shows an introduction step in the hydraulic jacking process. In this illustration the container 22 and its attached fill tube 24 are inserted into the vertebral body 10 together with the delivery tube 26. The assembly is positioned in the cavity 14 proximate the end of the cavity. In this step care must be taken to prevent pressurizing the device within the pedicle.

Fig. 9 shows a deployment step in the process. In this illustration the container is fully deployed in the cavity 14 by withdrawing the delivery tube (not shown) from the fill tube leaving the container 22 exposed in the cavity 14.

Fig. 10 shows an injection step in the process. The container 22 is filled through the fill tube 24 with a bone filler materials 36. The manual syringe 32 or other injection device injects the material at a sufficient pressure to create distraction forces shown in the figure a superior force 40 and inferior force 42. These forces are sufficient to move the endplate 20 and end plate 21 apart restoring height and angulation.

Fig. 11 shows a step of the process where an end point of the method is reached. Here the container 22 is completely filled and the original height of

the vertebral body is restored. This end point can be determined in any of several ways. For example an inelastic fixed volume container can be used and the injecting process stopped when resistance is felt through the hydraulic connection with the container. An alternate approach is the injection of a fixed volume of bone filler into an oversized elastic or porous container 22. Also the physician may follow the injection under fluoroscopy and limit injection through observation of a real time image in combination with medical judgement. In this instance the container can be inelastic or elastic. The final step in the typical method will be to remove the fill tube 24 from the container 22. This step will typically be performed after the bone filler 36 material is "step up" and no longer in a low viscosity state.

These initial figures depict the stabilization method and the hydraulic jacking method performed with substantially cylindrical containers. The membranes in the examples have all been impermeable to the bone filler. In these process the container may be elastic or inelastic as may be desired by the physician.

The stabilization method may be performed with all of the container devices shown.

The hydraulic jacking method can be performed with the all of the container devices with the exception of Fig. 13 and Fig. 14.

Fig. 12 shows an alternate container 22 with a membrane perforated by a series of holes typified by hole 44. When placed in a vertebral body the bone filler 36 extrudes from the holes and interdigitates with the cancellous bone 12 inside the vertebral body 10. It is difficult to illustrate this process but the cavity 14 has a wall that is porous so the bone filler interdigitates with the cancellous bone matrix.

Fig. 13 shows a tubular fixed diameter form of the container 22 which can be used to control the delivery of bone filler to the cavity. The container 22 approximates the size and shape of the cavity, prior to bone filler injection. The holes in the device distribute the bone filler to locations next to the holes.

Fig. 14 shows the container of Fig. 13 in operation in a vertebral body 10.

One preferred method of use which can be performed with porous containers involves the injection of a first volume of relatively less viscous bone filler to promote interdigitation of the cancellous bone. Next a second injection of bone filler material with a different mechanical strength or chemical composition is injected and it "pushes" against the initial or primary injected material. This technique produces a gradient of strength and elasticity through the repaired bone which mimics the mechanical characteristics of the natural bone. The relatively small diameter of this device allow the set of apertures to distribute the various bone filler materials without moving the device during injection.

Another preferred method involves the same two stage injection process with a non-porous or impermeable container. In this instance there is negligible interdigitation but the gradient remains.

Fig. 15 is a container with an asymmetrical distribution of holes so that the extrusion of bone filler occurs on one side of the container. This construction may allow the container to be moved within the vertebral body during injection of bone filler.

Fig. 16 shows an asymmetrical container 22 where hole size and distribution vary over the surface of the membrane. For example hole 44 is larger than holes 45 which lie along the axis of the fill tube 24. This asymmetry provides physician control of the distribution and the flow of the bone filler materials into specific regions of the vertebral body.

Fig. 17, Fig. 18 and Fig. 19 should be considered together. This group of drawings depicts an alternate "horseshoe" shape for the construction for the container 22. In each instance the fill tube has been eliminated from the figure to improve clarity. However it should be understood that at least one fill tube is used with each container in these figures. All of the container devices depicted in Fig. 17 through Fig. 20 can be made of porous or non-porous membrane materials.

Fig. 17 is single chamber fixed volume device 22 which may expand to a nominal height in the vertebral body 10.

Fig. 18 is a segmented horseshoe shaped container 22 device with a horizontal rib 70 that divides the container into two separate structures. The inner of the membrane 71 may be continuous with this rib 70 or weep holes may be provided to facilitate flow of bone filler within the device. The exterior surface of the membrane 73 may be porous or impermeable to bone filler. In this embodiment the rib 70 will effectively limit the height achieved in the vertebral body.

Fig. 19 is multi-chambered device with several lateral compartments created by ribs typified by rib 74. In this embodiment the chambers typified by chamber 75 limit the horizontal extent of the growth of the container during the hydraulic jacking process.

Fig. 20 is single chamber fixed volume device 22 with a triangular "footprint".

Fig. 21 is a segmented triangular device with a horizontal rib 76 defining two chambers.

Fig. 22 is multi-chambered device with several lateral compartments created by ribs typified by rib 77.

Fig. 23 shows an alternate tubular embodiment of a single chamber container 22 with a stylet 92 coupled to the most distal end of the container 22. This elongate tubular container is deployed by advancing the stylet 92 wire out of the delivery tube, which drags the container membrane out of the delivery tube 26 or the fill tube 24. In this device the container may be folded and placed entirely everted in the fill tube. This construction will allow the device to be safely delivered without the use of a delivery tube thereby maximizing the inner diameter of the fill tube.

Fig. 24 shows the alternate tubular embodiment of the container in its partially filled configuration. In this illustration the vertebral body 10 has had an oval cavity 14 formed in the cancellous bone. The stylet 92 is used to force

the container 22 along the outer wall path of the cavity 14 and it is then removed. Next bone filler material is injected through the fill tube and the annular ring tubular container is filled.

Fig. 25 shows a simple slip fit between the fill tube 24 and a complementary structure on the container 22. In this construction a septum 82 is used to fill the container 22 though a fill needle 84. One advantage of this construction is the septum seals the container and allows the container to seal while the bone filler hardens.

Fig. 26 shows are area or zone of weakness 83 in the fill tube 24 that preferentially breaks off to remove the fill tube from the container.

Fig. 27 the toothed member 85 circulates around the axis of the fill tube 24 and cuts of the fill tube away from the container after the bone filler has hardened.

Fig. 28 shows the container formed as a porous woven membrane 90. In use the bone filler 36 will exude from the area between the woven fibers to permeate the cancellous bone. The woven mesh will produce the same effect as an elastic membrane.

Various materials may be used to make the container including , polyethylene Teflon, Gore-Tex, polybutylene terephathlate, polyethylene terephathalate glycol, urethane and urethane coated materials. The material or the construction can give rise to elastic or inelastic structures both of which are operable in the methods of the invention. The woven embodiments of the porous container may also be made from metal meshes or screens including titanium, elgiloy MP35 nitinol, stainless steel, or other bio-compatible metals.

Various bone fillers contemplated within the scope of this invention. Bone fillers are defined for this disclosure as any substance used to stabilize the bone and includes but is not limited to bone cement, human bone graft (allograft autograft), synthetic derived bone substitutes such as calcium phosphate and hydroxylapatite. Bone fillers may be supplemented with other biologically active materials including but not limited to collagen

osteoinductive agents including bone morphogenic proteins. Other known ceramic based materials can be used as well. Other known bioresorbable polymers may be used as well.

Illustrative embodiments of the invention have been shown but numerous modifications may be made without departing from the scope of the invention which is defined by the appended claims.

What is claimed is:

1. An implantable device for insertion into a cavity in a vertebral body comprising:

a flexible container having a wall membrane:

said wall membrane defining an interior and an exterior of said container;

said wall having at least one hole connecting the interior with the exterior;

a fill tube coupled to said container at a location proximate an edge of said container for injecting a flowable or fluid bone filler material into said container such that said bone filler leaves said interior and enters said vertebral body.

2. The device of claim 1 wherein said container is substantially tubular in shape.

3. The device of claim 1 wherein said wall membrane is elastic.

4. The device of claim 1 wherein said wall membrane is inelastic.

5. The device of claim 1 wherein at least one of said wall membranes is woven.

6. The device of claim 1 wherein said wall membrane is porous.

7. The device of claim 1 wherein said wall membrane is not porous.

8. The device of claim 1 further comprising:

a septum located adjacent said container and in fluid communication with said interior for permitting the sealing entry of a filling device.

9. The device of claim 1 wherein said membrane is opaque to x-ray and is therefore radiopaque.

10. The device of claim 1 wherein said membrane is transparent to x-rays and is therefore radio-translucent.

11. The device of claim 1 further comprising a delivery tube, wherein said container is everted within said delivery tube.

12. An implantable device for insertion into a cavity in a vertebral body comprising:

a container including;

an upper wall member;

a lower wall member;

a circumfrential wall member;

a set of ribs extending from said upper wall to said lower wall, thereby forming a set of channels.

13. The device of claim 12 wherein said upper and lower wall member have a substantially horseshoe shape.

14 The device of claim 12 wherein said upper and lower wall member have a substantially triangular shape.

15. The device of claim 12 wherein said container is substantially cylindrical in shape.

16. The device of claim 12 wherein said wall membrane is elastic.

17. The device of claim 12 wherein said wall membrane is inelastic.

18. The device of claim 12 wherein at least one of said wall membranes is woven.

19. The device of claim 12 wherein said wall membrane is porous.

20. A method of treating an vertebral body having a superior endplate and an inferior endplate, comprising the steps of:

inserting a container into an vertebral body;

deploying said container within said vertebral body;

injecting a bone filler material into said container under pressure;

whereby said pressure supplies a distraction force to move said superior and inferior endplates apart;

ending injection after said endplates have moved apart.

21. The method of claim 20 wherein said filler material is selected from the group comprising:

bone cement, human bone graft allograft; human bone graft autograft; synthetic derived bone substitute; sulfate and/or calcium phosphate, hydroxylapatite.

22. A method of treating an vertebral body comprising the steps of:

creating a cavity in the vertebral body through an access aperture;

inserting a container into said vertebral body;

said container having a fill passage coupled to said container;

deploying said container within said vertebral body;

injecting a bone filler material into said container through said fill passage.

23. A method of treating an vertebral body comprising the steps of:

inserting a container into an vertebral body;

said container having a fill passage coupled to said container;

said container having a porous outer membrane sufficiently porous to allow filler material under pressure to leave the container after filling the container;

deploying said container within said vertebral body

injecting a filler material into said container through said fill passage with bone filler material in a sufficient volume to allow the bone filler material to exit the container and interdigitates with cancellous bone within said vertebral body thereby reinforcing said bone and stabilizing fractures in said bone;

said container membrane porosity sufficient to provide resistance to the flow of said bone filler material to generate force to move the endplates of said vertebral body.

24. The method of claim 23 wherein said injecting step is ended after the superior and inferior endplates move toward a normal anatomic position.

25. An implantable device for insertion into a cavity in a vertebral body comprising:

a container including;

an upper wall member;

a lower wall member;

a circumfrential wall member;

said wall members together defining a single chamber.

26. The device of claim 25 wherein said upper and lower wall member have a substantially horseshoe shape.

27. The device of claim 25 wherein said upper and lower wall member have a substantially triangular shape.

Abstract

An implantable container is used to stabilize or restore height in a vertebral body. After insertion the container is filled with a bone filler material such as bone cement.

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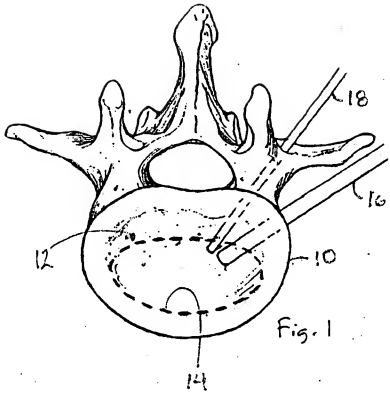


Fig. 1

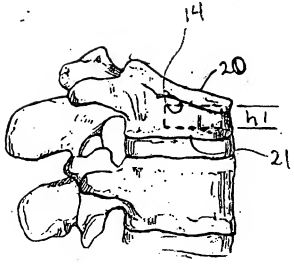


Fig. 2

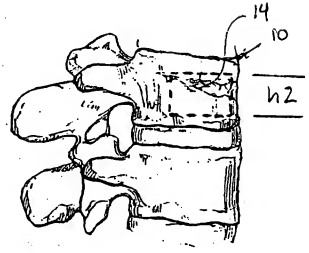


Fig. 3

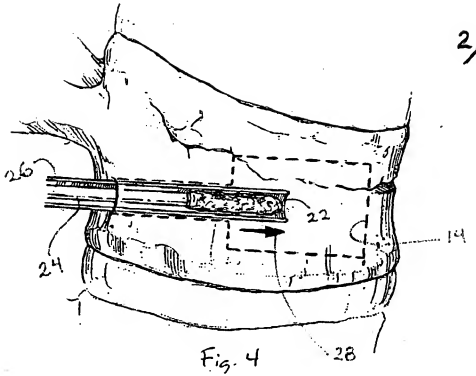


Fig. 4

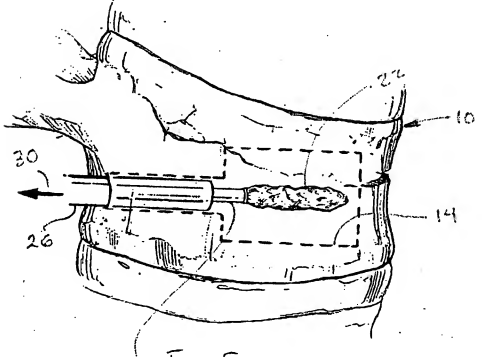


Fig. 5

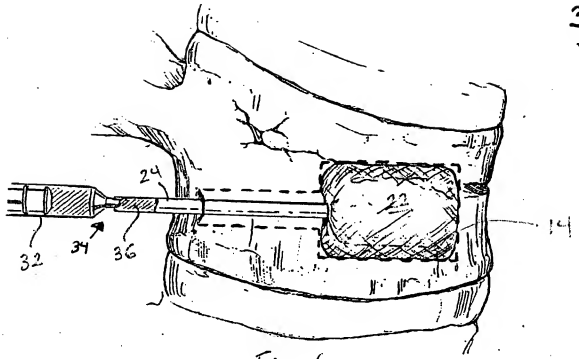


Fig. 6

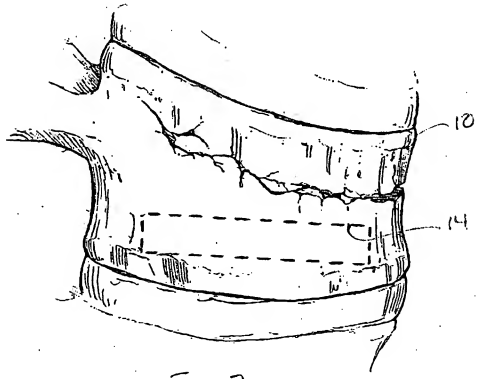


Fig. 7

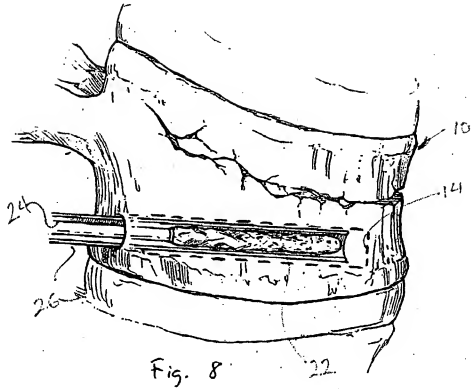


Fig. 8

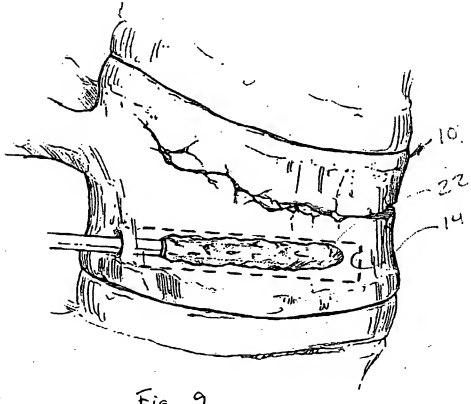


Fig. 9

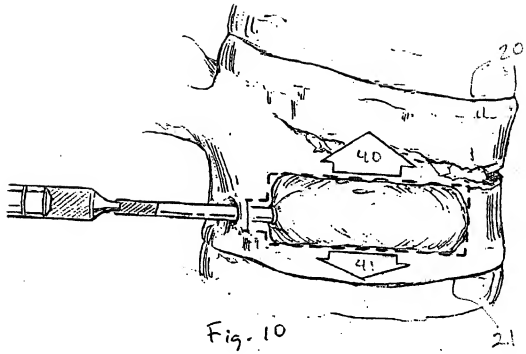


Fig. 10

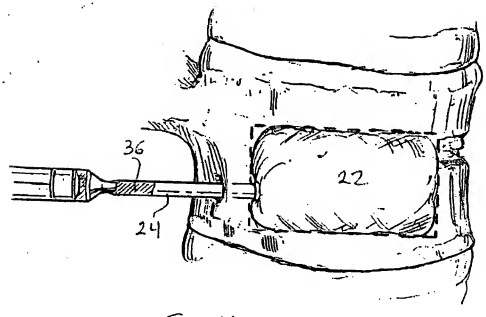


Fig. 11

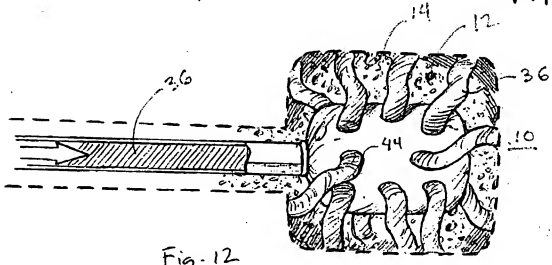


Fig. 12

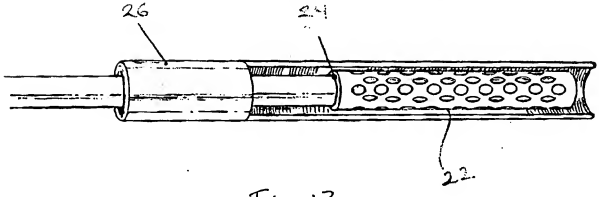


Fig. 13

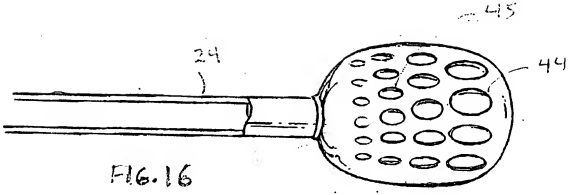


FIG. 16

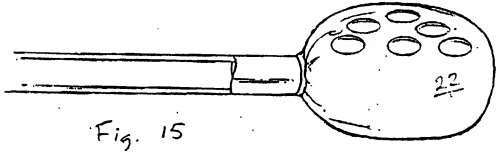


Fig. 15

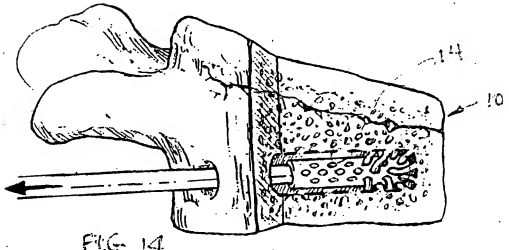


FIG. 14

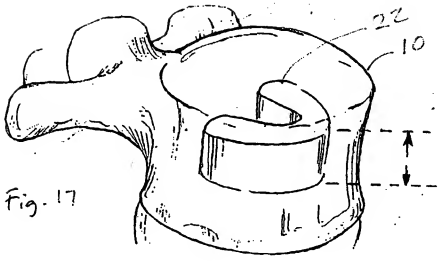


Fig. 17

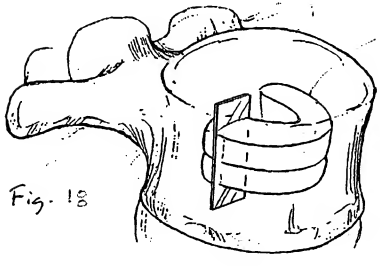
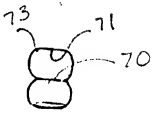


Fig. 18



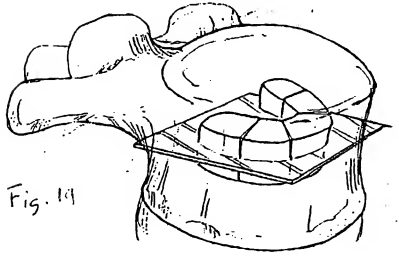
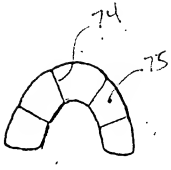


Fig. 19



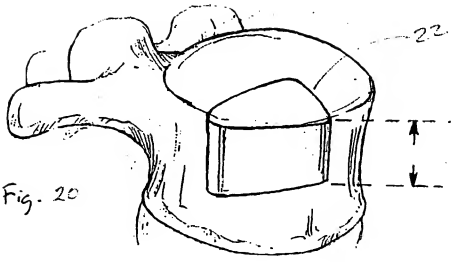


Fig. 20

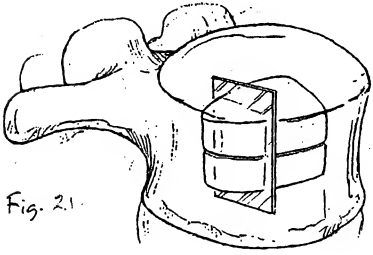
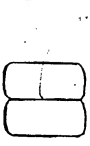


Fig. 21



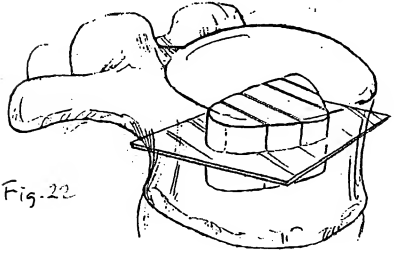
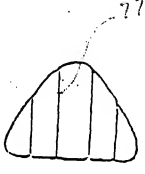


Fig. 22



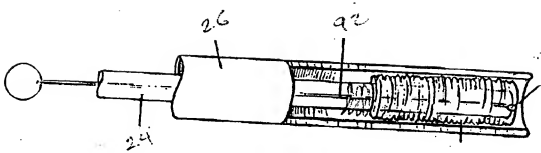


Fig. 23

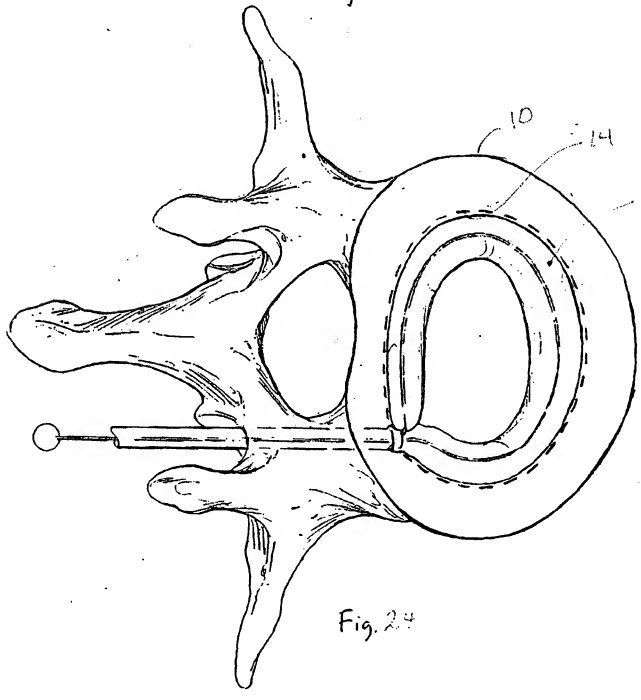


Fig. 24

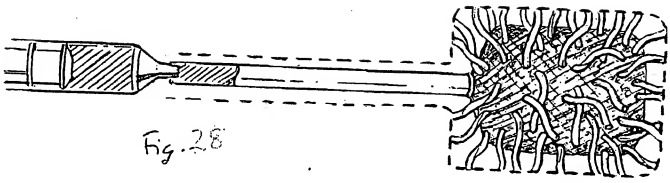


Fig. 28

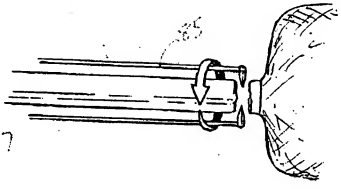


Fig. 27

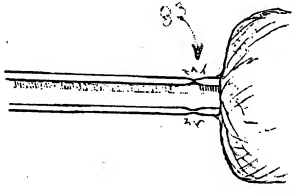


Fig. 26

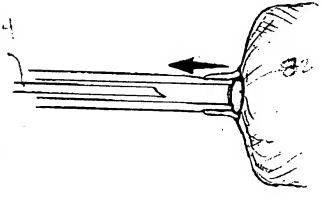


Fig. 25

Please type a plus sign (+) inside this box → [+]

PTO/SB/01 (10-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing **OR** ☑ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	2014
First Named Inventor	Hochschuler et al.
COMPLETE IF KNOWN	
Application Number	09 / 794,873
Filing Date	02/27/2001
Group Art Unit	3732
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHOD AND APPARATUS FOR TREATING A VERTEBRAL BODY

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☑ was filed on (MM/DD/YYYY) 02/27/2001 as United States Application Number or PCT International Application Number 09/794,873 and was amended on (MM/DD/YYYY) _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached? YES	Certified Copy Attached? NO
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐
			☐	☐	☐

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)
60/185,323	2/28/2000
60/220,303	07/24/2000
60/239,216	10/10/2000
60/239,217	10/10/2000

☐ Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Please type a plus sign (+) inside this box → [+]

PTO/SB/01 (10-00)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
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DECLARATION — Utility or Design Patent Application

Direct all correspondence to: ☐ Customer Number or Bar Code Label [ ] OR ☑ Correspondence address below

Name Robert C. Beck

Address Beck & Tysver, P.L.L.C.

Address 2900 Thomas Avenue South, Suite 100

City Minneapolis | State MN | ZIP 55416

Country USA | Telephone 612-915-9635 | Fax 612-915-9637

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]) Stephen | Family Name or Surname Hochschuler

Inventor's Signature [signature] | Date 11/6/01

Residence: City Dallas | State TX | USA Country | Citizenship USA

Mailing Address 17214 Club Hill Drive

Mailing Address

City Dallas | State TX | ZIP 75248 | Country USA

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]) Wesley | Family Name or Surname Johnson

Inventor's Signature [signature] | Date 11/9/01

Residence: City Eden Prairie | State MN | USA Country | Citizenship USA

Mailing Address 8091 Spruce Trail

Mailing Address

City Eden Prairie | State MN | ZIP 55347 | Country USA

☑ Additional inventors are being named on the ___ supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

Please type a plus sign (+) inside this box → +

PTO/SB/02A (3-97)
Approved for use through 9/30/98. OMB 0651-0032
Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION

ADDITIONAL INVENTOR(S) Supplemental Sheet
Page 1 of 2

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname				
Kevin L.			Nickels				
Inventor's Signature	Kevin L. Nickels					11/9/01 Date	
Residence: City	Bloomington	State MN	Country USA			Citizenship	USA
Post Office Address	8732 Walton Pond Circle						
Post Office Address							
City	Bloomington	State MN	ZIP 55438		Country	USA	

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname				
Thomas R.			Hektner				
Inventor's Signature	Thomas R. Hektner					9/11/01 Date	
Residence: City	Medina	State MN	Country USA			Citizenship	USA
Post Office Address	825 Navajo Road						
Post Office Address							
City	Medina	State MN	ZIP 55340		Country	USA	

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname				
Larry			Wales				
Inventor's Signature	Larry Wales					11/9/01 Date	
Residence: City	Maplewood	State MN	Country USA			Citizenship	USA
Post Office Address	1654 Currie Street						
Post Office Address							
City	Maplewood	State MN	ZIP 55119		Country	USA	

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PTO/SB/02A (3-97)
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Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION

ADDITIONAL INVENTOR(S)
Supplemental Sheet
Page 2 of 2

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])				Family Name or Surname			
Tyler				Lipschultz			
Inventor's Signature						**Date**	11/8/2001
Residence: City	Minneapolis	**State**	MN	**Country**	USA	**Citizenship**	USA
Post Office Address	15 South First St.						
Post Office Address	~~#A119~~ #A119						
City	Minneapolis	**State**	MN	**ZIP**	55401	**Country**	USA

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature						**Date**	
Residence: City		**State**		**Country**		**Citizenship**	
Post Office Address							
Post Office Address							
City		**State**		**ZIP**		**Country**	

Name of Additional Joint Inventor, if any:	☐ A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])				Family Name or Surname			
Inventor's Signature						**Date**	
Residence: City		**State**		**Country**		**Citizenship**	
Post Office Address							
Post Office Address							
City		**State**		**ZIP**		**Country**	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Boyd et al.	)	
	)	
Application No.: not yet assigned	)	Examiner: Not yet assigned
Divisional of Serial No. 09/794,873	)	
	)	
Filed: March 19, 2004	)	
	)	
DEVICES AND APPARATUS FOR	)	
TREATING A VERTEBRAL BODY	)	March 19, 2004

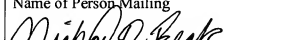
PRELIMINARY AMENDMENT

Mail Stop Patent Application
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

Prior to examination of the above-identified application, Applicants respectfully submit the following preliminary amendment.

"Express mail" mailing label number EV 389959275 US
Date of Deposit March 19, 2004
I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1. 10 on the date indicated above and is addressed to the Mail Stop Patent Application, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450
Michael D. Beck
Name of Person Mailing



Signature of Person Mailing

IN THE SPECIFICATION:

Please amend the first paragraph of the specification after the title as follows:

-- Cross-reference to related cases

This application is a divisional of co-pending application S.N. 09/794,873, filed on February 27, 2001, which ~~The present case~~ claims the benefit of the following Provisional Applications: "Cavity Sealing Barrier", Ser. No. 60/185,323, filed Feb. 28, 2000; "Implant for Hard Bones", Ser. No. 60/220,303, filed Jul. 24, 2000; "Vertebral Body Sealing Device and Method", Ser. No. 60/239,216, filed Oct. 10, 2000; "Hydraulic Distraction with Permeable Membrane", Ser. No. 60/239,217, filed Oct. 10, 2000 and incorporates each of these by reference in their entirety. - -

IN THE CLAIMS:

Please cancel claims 20-24.

Please amend claims 1, 8-10, 12-19 and 25-27 as indicated below.

Please add new claims 28-33 as indicated below.

A complete listing of the claims and their status follows.

1. (currently amended) An implantable device for insertion into a cavity in a vertebral body comprising:

a ~~flexible~~ container having a wall membrane~~;~~,

said wall membrane defining an interior and an exterior of said container~~;~~ ~~said wall having~~ and at least one hole connecting the interior with the exterior; and

a fill tube coupled to said container at a location proximate an edge of said container for injecting a flowable ~~or fluid~~ bone filler material into said container such that said bone filler leaves said interior and enters said vertebral body.

2. (original) The device of claim 1 wherein said container is substantially tubular in shape.

3. (original) The device of claim 1 wherein said wall membrane is elastic.

4. (original) The device of claim 1 wherein said wall membrane is inelastic.

5. (original) The device of claim 1 wherein at least one of said wall membranes is woven.

6. (original) The device of claim 1 wherein said wall membrane is porous.

7. (original) The device of claim 1 wherein said wall membrane is not porous.

8. (currently amended) The device of claim 1 further comprising: a septum located adjacent said container and in fluid communication with said interior for permitting the sealing entry of a filling device.

9. (currently amended) The device of claim 1 wherein said membrane is ~~opaque to x-ray and is therefore~~ radiopaque.

10. (currently amended) The device of claim 1 wherein said membrane is ~~transparent to x-rays and is therefore~~ radio-translucent.

11. (original) The device of claim 1 further comprising a delivery tube, wherein said container is everted within said delivery tube.

12. (currently amended) An implantable device for insertion into a cavity in a vertebral body comprising:

~~a container including;~~ an upper wall member;

a lower wall member;

a ~~circumfrential~~ circumferential wall member connecting said upper wall member and said lower wall member; and

a set of ribs extending ~~from~~ between said upper wall member ~~to~~ and said lower wall member, ~~thereby~~ forming a set of ~~channels~~ compartments therebetween.

13. (currently amended) The device of claim 12 wherein said upper and lower wall ~~member~~ members have a substantially horseshoe shape.

14. (currently amended) The device of claim 12 wherein said upper and lower wall ~~member~~ members have a substantially triangular shape.

15. (currently amended) The device of claim 12 wherein said upper, lower and circumferential wall members define a container that is substantially cylindrical in shape.

16. (currently amended) The device of claim 12 wherein at least said circumferential wall ~~membrane~~ member is elastic.

17. (currently amended) The device of claim 12 wherein at least said circumferential wall ~~membrane~~ member is inelastic.

18. (currently amended) The device of claim 12 wherein at least one of said upper, lower and circumferential walls ~~wall membranes~~ is woven.

19. (currently amended) The device of claim 12 wherein at least one of said upper, lower and circumferential walls ~~wall membrane~~ is porous.

Claims 20-24 (cancelled)

25. (currently amended) An implantable device for insertion into a cavity in a vertebral body comprising~~:~~ a an expandable container including; an upper wall member~~;~~, a lower wall member~~;~~, and a ~~circumfrential~~ circumferential wall member~~;~~, said wall members together defining a single chamber.

26. (currently amended) The device of claim 25 wherein said upper and lower wall ~~member~~ members have a substantially horseshoe shape.

27. (currently amended) The device of claim 25 wherein said upper and lower wall ~~member~~ members have a substantially triangular shape.

28. (new) The device of claim 1, wherein said container is expandable under pressure from the flowable bone filler injected into said container.

29. (new) The device of claim 28, wherein said container is expandable from a first configuration sized for percutaneous introduction through a cannula to a larger second configuration sized to fill the cavity in the vertebral body.

30. (new) The device of claim 1, wherein said fill tube is removably coupled to said container.

31. (new) The device of claim 30, wherein said fill tube includes an area of weakness adjacent said container adapted to break to remove said fill tube from said container.

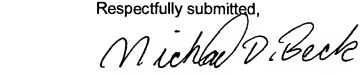
32. (new) The device of claim 6, wherein said wall defines a plurality of holes symmetrically disposed about said container.

33. (new) The device of claim 6, wherein said wall defines a plurality of holes asymmetrically disposed about said container.

REMARKS

Consideration of the present application with the amended and newly added claims is requested. The Examiner is invited to contact the undersigned if it is believed that a telephonic interview will be helpful to advance this application to issuance.

Respectfully submitted,



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(317) 638-2922 (phone)
(317) 638-2139 (fax)
mdbeck@maginot.com

Application Data Sheet

Application Information

Application Type:: Regular

Subject Matter:: Utility

Suggested Classification::

Suggested Group Art Unit::

CD-ROM or CD-R?:: None

Title:: Method and Apparatus for Treating a Vertebral Body

Request for Early Publication?:: No

Request for Non-Publication?:: No

Suggested Drawing Figure:: 10

Total Drawing Sheets:: 11

Small Entity:: No

Petition included?:: No

Secrecy Order in Parent Appl.?:: No

Applicant Information

Applicant Authority type:: Inventor

Primary Citizenship Country: US

Status:: Full Capacity

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Family Name:: Hochschuler

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State or Province of Residence:: TX

Country of Residence:: US

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Applicant Information

Applicant Authority type:: Inventor

Primary Citizenship Country: US

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Country of Residence:: US

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State or Province of mailing address:: MN

Postal or Zip Code of mailing address:: 55347

Applicant Information

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Primary Citizenship Country: US

Status:: Full Capacity

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State or Province of mailing address:: MN

Postal or Zip Code of mailing address:: 55340

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Applicant Authority type:: Inventor

Primary Citizenship Country: US

Status:: Full Capacity

Given Name: Larry.

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Country of Residence:: US

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City of mailing address:: Maplewood

State or Province of mailing address:: MN

Postal or Zip Code of mailing address:: 55119

Applicant Information

Applicant Authority type:: Inventor

Primary Citizenship Country: US

Status:: Full Capacity

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State or Province of Residence:: CT

Country of Residence:: US

Street of mailing address:: 6112 Avalon Drive East

City of mailing address:: New Canaan

State or Province of mailing address:: CT

Postal or Zip Code of mailing address:: 06840

Correspondence Information

Correspondence Customer Number:: 28078

Name::	Michael D. Beck
Street of mailing Address::	111 Monument Circle, Suite 3000
City of mailing Address::	Indianapolis
State or Province of mailing address::	IN
Country of mailing address::	US
Postal or Zip Code of mailing address::	46204-5115
Phone number::	317-638-2922
Fax number::	317-638-2139
E-mail address::	mdbeck@maginot.com

Representative Information

Representative Customer Number:	28078

Domestic Priority Information

Application::	Continuity Type:	Parent Application::	Parent Filing Date::
	Divisional	09/794,873	02/27/2001

PATENT APPLICATION FEE DETERMINATION RECORD
Effective October 1, 2003

Application or Docket Number
10/0495

CLAIMS AS FILED - PART I

	(Column 1)	(Column 2)
TOTAL CLAIMS	28	
FOR	NUMBER FILED	NUMBER EXTRA
TOTAL CHARGEABLE CLAIMS	28 minus 20=	* 8
INDEPENDENT CLAIMS	3 minus 3 =	*
MULTIPLE DEPENDENT CLAIM PRESENT		☐

* If the difference in column 1 is less than zero, enter "0" in column 2

SMALL ENTITY TYPE ☐		OR	OTHER THAN SMALL ENTITY	
RATE	FEE		RATE	FEE
BASIC FEE	385.00	OR	BASIC FEE	770.00
X$ 9=	72	OR	X$18=	
X43=		OR	X86=	
+145=		OR	+290=	
TOTAL	495	OR	TOTAL	

CLAIMS AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

SMALL ENTITY		OR	OTHER THAN SMALL ENTITY	
RATE	ADDI-TIONAL FEE		RATE	ADDI-TIONAL FEE
X$ 9=		OR	X$18=	
X43=		OR	X86=	
+145=		OR	+290=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDI-TIONAL FEE		RATE	ADDI-TIONAL FEE
X$ 9=		OR	X$18=	
X43=		OR	X86=	
+145=		OR	+290=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

AMENDMENT C

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA
Total	*	Minus	**	=
Independent	*	Minus	***	=
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM				☐

RATE	ADDI-TIONAL FEE		RATE	ADDI-TIONAL FEE
X$ 9=		OR	X$18=	
X43=		OR	X86=	
+145=		OR	+290=	
TOTAL ADDIT. FEE		OR	TOTAL ADDIT. FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20."
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3."
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.

PATENT APPLICATION SERIAL NO. _____

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

03/23/2004 SSITHIB1 00000061 10804955

01 FC:2001 385.00 OP
02 FC:2202 72.00 OP

PTO-1556
(5/87)

U.S. Government Printing Office: 2001 — 481-697-55173